NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of optical coherence tomography to guide percutaneous coronary intervention

Optical coherence tomography (OCT) is a method for creating images of the inside of blood vessels. A thin flexible tube (a catheter) with a tip emitting near-infrared light is inserted into an artery in the groin or arm under local anaesthetic, in the same way as the balloon catheters and stents used to treat narrowing in the coronary arteries (that supply blood to the heart). The OCT images help to make decisions about treatment or show how well balloon and stent treatment has worked.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in May 2013 and updated with information requested by IPAC in August 2013.

Procedure name

- Optical coherence tomography to guide percutaneous coronary intervention

Specialist societies

- British Cardiovascular Intervention Society
- British Cardiovascular Society.

Description

Indications and current treatment

Optical coherence tomography (OCT) uses a catheter emitting near-infrared light to produce high-resolution images of blood vessel walls. It may be used to assess stenotic lesions in the coronary arteries and to image the result of stent deployment during percutaneous coronary interventions.

Coronary angiography is used to image coronary arteries immediately before angioplasty. Intravascular ultrasound or OCT may be used to provide additional and complementary information to coronary angiography.

What the procedure involves

Optical coherence tomography (OCT) is usually performed using local anaesthesia. A guide wire and delivery sheath are introduced percutaneously into either the femoral or radial artery and passed into the target coronary artery using fluoroscopic image guidance. OCT imaging needs a blood-free field. This was first achieved by an occlusive technique, using an occlusion balloon with first-generation time-domain OCT (TD-OCT), but this technique is no longer used in clinical practice. A non-occlusive technique is now used, involving continuous flushing of contrast with frequency-domain OCT (FD-OCT). For non-occlusive OCT, a guide wire through which contrast can be injected is used. The imaging catheter is delivered over this wire. Injection of contrast and imaging take place concurrently.

Second-generation FD-OCT devices aim to improve image quality and, more importantly, increase the speed of image acquisition by a factor of 10. FD-OCT has superseded TD-OCT in the UK.

The resolution of coronary OCT is reported to be 10 times higher than that of intravascular ultrasound, and has rapid 3-dimensional reconstruction capability. The aim of providing more detailed images is to improve clinical outcome.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to optical coherence tomography to guide percutaneous coronary intervention. Searches were conducted of the following databases, covering the period from their commencement to 1 May 2013: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases, Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	**Criteria**
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients needing intravascular coronary imaging.
Intervention/test	Optical coherence tomography.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This IP overview is based on approximately 1692 patients from 1 RCT, 3 comparative studies, 5 case series and 5 case studies.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on optical coherence tomography to guide percutaneous coronary intervention

<table>
<tr><td colspan="4">Abbreviations used: angio, angiography; DES, drug-eluting stent; FD-OCT, frequency-domain optical coherence tomography; MI, myocardial infarction; OCT, optical coherence tomography; PCI, percutaneous coronary intervention</td></tr>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Prati, F (2012)[1]

Retrospective matched case control study
Italy
Recruitment period: 2009-2011
Study population: Consecutive patients undergoing PCI with angiography plus OCT guidance (OCT group) matched patients undergoing PCI with angiography only guidance within 30 days and in the same institution (angio group)
n = 670 (335 FD-OCT + angio vs 335 angio only)
Age: 65.9 years
Sex: 76.9% male

Patient selection criteria: Operational, not experimental. Specific selection criteria not reported

Technique: FD-OCT images</td>
<td>Number of patients analysed: 670 (335 FD-OCT + angio vs. 335 Angio only)

<i>Clinical decision-making</i>
OCT findings led to additional interventions in 34.7% of the subjects:
• further stenting in 12.6% of cases (5.4% for an edge dissection, 7.2% to enlarge a reference lumen area that was <4 mm^2).
• additional balloon dilatation in 22.1% of cases (14.0% for stent under-expansion, 8.1% for intra-stent thrombus).

<i>Clinical outcomes</i>
<table>
<tr><th></th><th>Angio group</th><th>OCT group</th><th>p-value</th></tr>
<tr><td>In-hospital events</td><td>n (%)</td><td>n (%)</td><td></td></tr>
<tr><td>Cardiac death</td><td>3 (0.9%)</td><td>2 (0.6%)</td><td>1.0</td></tr>
<tr><td>Non-fatal MI</td><td>22 (6.5%)</td><td>13 (3.9%)</td><td>0.118</td></tr>
<tr><td>Events at 1-year follow-up</td><td></td><td></td><td></td></tr>
<tr><td>Total deaths</td><td>23 (6.9%)</td><td>11 (3.3%)</td><td>0.035</td></tr>
<tr><td>Cardiac death</td><td>15 (4.5%)</td><td>4 (1.2%)</td><td>0.010</td></tr>
<tr><td>MI</td><td>29</td><td>18</td><td>0.096</td></tr>
</table>
</td>
<td>Acquisition of OCT imaging was not associated with any major complication, as no case of significant spasm, dissection or life-threatening arrhythmia occurred (that is, requiring pharmacologic therapy, revascularisation, or cardioversion/defibrillation).

Accordingly, no significant differences in post-procedural renal function were found comparing the OCT group with the angio group.</td>
<td>Follow-up issues:
• Patients were followed up at 1-3 and 6 months. All patients were questioned by a research nurse between 11.5 and 12.5 months after the index procedure.
Study design issues:
• Treatment choices were at the operator's discretion.
• The use of OCT guidance for coronary angioplasty was left at the operator's discretion, with some preferring either OCT guidance or angiographic guidance alone for most of their cases.
• The authors report that patients in the OCT group were matched with a randomly selected patient undergoing PCI, without OCT guidance, at the same institution within 30 days but do not include details of randomisation.

Study population issues:
• Patients in the angio group were older (67.0 vs. 64.8 years, p=0.016), more frequently presented with ST-elevation MI (36.7% vs. 25.7%, p=0.005), type B2/C lesions (86.7% vs. 72.8%, p<0.001) and were less likely to be treated with DES (43.6% vs. 63.3%,</td>
</tr>
</table>

<table>
<tr><td colspan="4">Abbreviations used: angio, angiography; DES, drug-eluting stent; FD-OCT, frequency-domain optical coherence tomography; MI, myocardial infarction; OCT, optical coherence tomography; PCI, percutaneous coronary intervention</td></tr>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>were acquired with the C7 XR system (LightLab, St Jude Medical).

All procedures were carried out by senior staff members with established skills and case-load.

Follow-up: 1 year

Conflict of interest/source of funding: the authors have no conflicts of interest to declare. The study was funded by Centro per la Lotta contro l’Infarto.</td>
<td>
<table>
<tr><td></td><td>(8.7%)</td><td>(5.4%)</td><td></td></tr>
<tr><td>Target lesion repeat revascularisation</td><td>11 (3.3%)</td><td>11 (3.3%)</td><td>1.0</td></tr>
<tr><td>Definite stent thrombosis</td><td>2 (0.6%)</td><td>1 (0.3%)</td><td>1.0</td></tr>
<tr><td>Cardiac death or MI</td><td>43 (13.0%)</td><td>22 (6.6%)</td><td>0.006</td></tr>
<tr><td>Cardiac death, MI or repeat revascularisation</td><td>50 (15.1%)</td><td>32 (9.6%)</td><td>0.034</td></tr>
</table>

OCT and survival: multivariate analysis
Multivariate analysis adjusted for all covariates associated with the OCT group at p<0.05
<table>
<tr><th></th><th>Cardiac death or MI in OCT group
OR (95% CI)</th><th>p-value</th></tr>
<tr><td>Multivariate logistic regression</td><td>0.49 (0.25-0.96)</td><td>0.037</td></tr>
<tr><td>+propensity score matching and bootstrap re-sampling</td><td>0.37 (0.10-0.90)</td><td>0.050</td></tr>
<tr><td>Cox proportional hazards model</td><td>0.51 (0.28-0.93)</td><td>0.028</td></tr>
<tr><td>+propensity score matching and bootstrap re-sampling</td><td>0.44 (0.21-0.92)</td><td>0.030</td></tr>
</table>
</td>
<td></td>
<td>p<0.001).
• Conversely, subjects in the OCT group had a higher prevalence of non-ST-elevation acute coronary syndromes (33.4% vs. 25.4%, p=0.005), dyslipidaemia (53.3% vs. 64.5%, p=0.002), prior PCI (23.5% vs. 34.3%, p=0.002), multivessel disease (52.1% vs. 63.2%, p=0.007), and left main disease (2.4% vs. 6.6%, p=0.009), more frequently received treatment on the left anterior descending (53.4% vs. 60.9%, p=0.050) or multiple vessels (15.5% vs. 23.3%, p=0.011), had longer total stent length (26.0±15.6 mm vs. 29.0±16.6 mm, p=0.024), and more frequently received overlapping stents (7.5% vs. 14.6%, p=0.003) and larger balloons (3.0±0.5 mm vs. 3.1±0.4 mm, p=0.037).</td>
</tr>
</table>

<table>
<tr><td colspan="4">Abbreviations used: EEM, external elastic membrane; FD-OCT, frequency-domain optical coherence tomography; IVUS, intravascular ultrasound; MI, myocardial infarction; MLA, minimum lumen area; MSA, minimum stent area; N/A, not applicable; OCT, optical coherence tomography; QCA, quantitative coronary angiography.</td></tr>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>
Habara, M (2012)[2]

Randomised controlled trial
Japan
Recruitment period: 2010
Study population: patients with new coronary artery lesions and either unstable or stable angina pectoris.
n = **70 (35 OCT vs. 35 IVUS)**
Age: 67.5 years
Sex: 78.6% male

Patient selection criteria:

Inclusion criteria: patients with symptomatic ischaemic heart disease; a new lesion in the native coronary circulation detected by coronary angiography; and planned stent implantation.

Exclusion criteria: left main coronary artery disease; totally occluded lesion; lesion length >25mm analysed by QCA; bifurcation lesion; lesion of vessel with diameter >3.5mm (analysed by QCA); lesion of severe tortuous vessel; cardiogenic shock; left ventricular ejection fraction <30%; serum creatinine >2mg/dL; ST elevation MI; use of aspirin, ticlopidine or heparin contraindicated.
</td>
<td>
Number of patients analysed: **70 (35 OCT vs. 35 IVUS)**
Procedural Outcomes
<table>
<tr><th></th><th>OCT</th><th>IVUS</th><th>p value</th></tr>
<tr><td>Total fluoroscopy time (minutes)</td><td>20.4±8.4</td><td>24.8±10.4</td><td>0.05</td></tr>
<tr><td>Device success* (%)</td><td>100%</td><td>100%</td><td>>0.99</td></tr>
<tr><td>Clinical success[a] (%)</td><td>91.4%</td><td>85.7%</td><td>0.71</td></tr>
<tr><td colspan="4">Good vessel border visibility (%)</td></tr>
<tr><td>At proximal ref</td><td>62.9%</td><td>100%</td><td><0.001</td></tr>
<tr><td>At MLA site</td><td>8.6%</td><td>94.3%</td><td><0.001</td></tr>
<tr><td>At distal ref</td><td>62.9%</td><td>100%</td><td><0.001</td></tr>
<tr><td>At MSA site</td><td>11.4%</td><td>94.3%</td><td><0.001</td></tr>
</table>
*defined as imaging obtained when devices crossed through the lesion to the distal location.
[a]defined as final lesion diameter stenosis <30% without a major in-hospital cardiac event.

Optimisation of Stent Results
<table>
<tr><th></th><th>OCT Mean±SD</th><th>IVUS Mean±SD</th><th>p value</th></tr>
<tr><td colspan="4">Post procedure QCA analysis</td></tr>
<tr><td>Post % diameter stenosis</td><td>7.7±5.8</td><td>5.0±4.5</td><td>0.03</td></tr>
<tr><td colspan="4">Post procedure IVUS analysis</td></tr>
<tr><td>MSA mm^2</td><td>6.1±2.2</td><td>7.1±2.1</td><td>0.04</td></tr>
<tr><td>Mean stent area mm^2</td><td>7.5+2.5</td><td>8.7+2.4</td><td>0.04</td></tr>
<tr><td>Focal stent expansion %</td><td>64.7+13.7</td><td>80.3+13.4</td><td>0.002</td></tr>
<tr><td>Diffuse stent</td><td>84.2+15.8</td><td>98.8+16.5</td><td>0.003</td></tr>
</table>
</td>
<td>
No complications associated with the imaging procedure were observed in either group.

Adverse events
<table>
<tr><th></th><th>OCT n (%)</th><th>IVUS n(%)</th><th>p value</th></tr>
<tr><td>Death</td><td>0</td><td>0</td><td>N/A</td></tr>
<tr><td>Emergency revascularisation</td><td>0</td><td>0</td><td>N/A</td></tr>
<tr><td>Q-wave MI (due to side-branch occlusion in the OCT patient; due to distal embolism in the IVUS patient)</td><td>1 (2.9)</td><td>1 (2.9)</td><td>N/A</td></tr>
<tr><td>Non-Q-wave MI(all were attributed to distal embolus)</td><td>1 (2.9)</td><td>4 (11.4)</td><td>0.36</td></tr>
<tr><td>Life-threatening arrhythmia</td><td>0</td><td>0</td><td>N/A</td></tr>
<tr><td>Coronary dissection</td><td>1 (2.9)</td><td>0</td><td>N/A</td></tr>
<tr><td>Prolonged and severe vessel spasm</td><td>0</td><td>0</td><td>N/A</td></tr>
<tr><td>Distal embolus (leading to MI, see above)</td><td>1 (2.9)</td><td>5 (14.2)</td><td>0.2</td></tr>
</table>
</td>
<td>
Study design issues:
- Randomisation by sealed envelopes.
- Blinding was not possible for either investigator or subject; however, QCA measurements were done by a single operator blinded to clinical characteristics.
- Quantitative OCT and IVUS analysis were also performed by an independent experienced observer blinded to clinical and angiographic lesion characteristics.
- Where the vessel border was not visible at both reference segments, stent length and diameter were decided by angiography.
- Where the vessel border was not visible at MLA site, stent deployment pressure was decided by angiography.

Study population issues:
</td>
</tr>
</table>

<table>
<tr><td colspan="4">Abbreviations used: EEM, external elastic membrane; FD-OCT, frequency-domain optical coherence tomography; IVUS, intravascular ultrasound; MI, myocardial infarction; MLA, minimum lumen area; MSA, minimum stent area; N/A, not applicable; OCT, optical coherence tomography; QCA, quantitative coronary angiography.</td></tr>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Technique: FD-OCT was performed using the Light Lab OCT system. IVUS was performed using an IVUS catheter by Boston Scientific Corporation and commercially available software by Indec Systems to review the images.

Follow-up: not applicable

Conflict of interest/source of funding: not stated</td>
<td>
<table>
<tr><td>expansion %</td><td></td><td></td><td></td></tr>
<tr><td>Mean reference lumen area mm^2</td><td>9.2+3.3</td><td>9.1+3.1</td><td>0.98</td></tr>
<tr><td>EEM at MSA site mm^2</td><td>12.9+5.2</td><td>12.6+4.3</td><td>0.82</td></tr>
<tr><td>Residual plaque burden at MSA site %</td><td>50.7+11.3</td><td>41.8+9.1</td><td><0.001</td></tr>
</table>

Other significant results include plaque burden at the proximal edge (p<0.05). MSA was also significantly different as assessed by post-procedure OCT (p=0.03).</td>
<td></td>
<td>• Baseline demographics, clinical data, and angiographic characteristics including QCA findings were similar between groups.</td>
</tr>
</table>

<table>
<tr><td colspan="4">Abbreviations used: CABG, coronary artery bypass graft; ECG, electrocardiogram; FD-OCT, frequency-domain optical coherence tomography; IVUS, intravascular ultrasound; OCT, optical coherence tomography; PCI, percutaneous coronary intervention</td></tr>
<tr><td>Study details</td><td>Key efficacy findings</td><td>Key safety findings</td><td>Comments</td></tr>
<tr>
<td>Imola, F (2010)[3]

Case series
Italy
Recruitment period: 2009
Study population: 40 patients with ambiguous/intermediate lesions; 50 patients to address adequacy of stent deployment
n = 90 patients; 114 OCT acquisitions
Age: 67 years
Sex: 73.4% male

Patient selection criteria: patients referred for coronary angioplasty with silent ischaemia, stable angina or acute coronary syndrome.

Exclusion criteria: presence of cardiogenic shock, renal insufficiency or coexistent condition associated with limited life expectancy.

Technique: FD-OCT was achieved with the LightLab system.

Follow-up: 4.6 months (average)

Conflict of interest/source of funding: the authors have no conflicts of interest</td>
<td>Number of patients analysed: 90 patients, 114 OCT acquisitions

<i>Procedural outcome</i>
The procedure was successful in 99.1% of patients (unsuccessful in 1 due to the OCT probe being stuck at the site of two overlapping stents).

<i>Clinical decision making</i>
Pre-intervention OCT was performed to evaluate ambiguous/intermediate lesions in 40 patients. Based on OCT findings, 24 were treated with PCI and 16 had PCI deferred.

Stent assessment was performed in 74 patients. OCT findings led to additional interventions in 24 out of 74 patients. 15 had further balloon inflations, 9 had additional stent deployment, while 2 had both treatments.

<i>Clinical follow-up (n=88)</i>
<table>
<tr><th></th><th>n</th><th>%</th></tr>
<tr><td>Death</td><td>0</td><td></td></tr>
<tr><td>MI</td><td>0</td><td></td></tr>
<tr><td>Angina recurrence</td><td>3</td><td>3.4%</td></tr>
<tr><td>CABG</td><td>1</td><td>1.1%</td></tr>
<tr><td>Re-PCI</td><td>1</td><td>1.1%</td></tr>
</table>

No patient in whom PCI was deferred based on OCT findings experienced any coronary events. These 16 patients were symptom free at follow-up.</td>
<td>
<table>
<tr><th>Adverse event</th><th>n</th></tr>
<tr><td>Transient vessel spasm, resolved with intra-coronary nitrates</td><td>1</td></tr>
<tr><td>Ischaemic ECG changes</td><td>0</td></tr>
<tr><td>Ventricular ectopic beats (found during contrast infusion for blood clearance)</td><td>3</td></tr>
<tr><td>Other major arrhythmias (ventricular tachycardia or fibrillation)</td><td>0</td></tr>
</table>
</td>
<td>Follow-up issues:
• 2 patients lost to follow-up
• The minimum duration of follow-up was 1 month only.

Study design issues:
• Non-consecutive patients
• No comparison group with which to compare event rates during clinical follow-up
• Patients with calcified and tortuous vessels were included in this study.</td>
</tr>
</table>

<table>
<tr><td colspan="4">Abbreviations used: ACS, acute coronary syndrome; AF, atrial fibrillation; OCT, optical coherence tomography; STEMI, ST-elevation; MI, myocardial infarction; TD-OCT, time domain optical coherence tomography.</td></tr>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Barlis, P (2009)[4]

Retrospective case series
The Netherlands, UK, Italy, Germany
Recruitment period: before 2008
Study population: 248 with stable angina, 121 unstable angina, 99 ACS/STEMI
n = 468
Age: 63.7 years
Sex: 78.4% male

Patient selection criteria: Consecutive patients who had OCT before 31 January 2008.

Technique: TD-OCT imaging was acquired using a LightLab imaging system; non-occlusive and occlusive using a balloon were used depending on the centre.

Follow-up: 24 hours

Conflict of interest/source of funding: the authors have no conflicts of interest</td>
<td>Number of patients analysed: 468</td>
<td>
<table>
<tr><th></th><th>All (468)</th><th>Occlusive technique (256)</th><th>Non-occlusive technique (212)</th><th>p-value</th></tr>
<tr><td colspan="5">Self-limiting events %</td></tr>
<tr><td>Chest pain</td><td>47.6</td><td>69.9</td><td>20.8</td><td><0.001</td></tr>
<tr><td>Widening QRS/ST depression</td><td>41.0</td><td>54.3</td><td>25</td><td><0.001</td></tr>
<tr><td>ST elevation</td><td>4.5</td><td>6.6</td><td>1.9</td><td>0.01</td></tr>
<tr><td>Sinus bradycardia</td><td>3.0</td><td>4.3</td><td>1.4</td><td>0.07</td></tr>
<tr><td>Sinus tachycardia</td><td>2.1</td><td>2.7</td><td>1.4</td><td>0.33</td></tr>
<tr><td>Atrioventricular shock</td><td>0.4</td><td>0.8</td><td>0</td><td>0.19</td></tr>
<tr><td colspan="5">Major complications n (%)</td></tr>
<tr><td>AF</td><td>0</td><td>0</td><td>0</td><td>-</td></tr>
<tr><td>Ventricular tachycardia</td><td>0</td><td>0</td><td>0</td><td>-</td></tr>
<tr><td>Ventricular fibrillation</td><td>5 (1.1)</td><td>3 (1.2)</td><td>2 (0.9)</td><td>0.81</td></tr>
<tr><td>Coronary spasm</td><td>0</td><td>0</td><td>0</td><td>-</td></tr>
<tr><td>Dissection</td><td>1 (0.2)</td><td>1 (0.4)</td><td>0</td><td>0.36</td></tr>
<tr><td>Perforation</td><td>0</td><td>0</td><td>0</td><td>-</td></tr>
<tr><td>Thrombus</td><td>0</td><td>0</td><td>0</td><td>-</td></tr>
<tr><td>Air embolism</td><td>3 (0.6)</td><td>2 (0.8)</td><td>1 (0.5)</td><td>0.68</td></tr>
<tr><td>Mechanical device failure</td><td>1 (0.2)</td><td>0</td><td>1 (0.5)</td><td>0.45</td></tr>
<tr><td>Major adverse cardiac events</td><td>0</td><td>0</td><td>0</td><td>-</td></tr>
</table>

Outcomes of adverse events: 96.7% immediate resolution; 3.1% required specific treatment but resolved before leaving the catheterisation laboratory; 0.2% persisted beyond discharge from catheterisation laboratory and ongoing clinical surveillance.
</td>
<td>Study design issues:
• Study includes cases from 6 centres.
• Study includes all OCT cases before 31 January 2008, including cases from the earliest phase of OCT development.</td>
</tr>
</table>

<table>
<tr><td colspan="4">Abbreviations used: ACS, acute coronary syndrome; CI, confidence interval; NSCP, non-significant coronary plaque; OCT, optical coherence tomography; OR, odds ratio; PCI, percutaneous coronary intervention; TCFA, thin-cap fibroatheroma; TD-OCT, time-domain optical coherence tomography</td></tr>
<tr><td>Study details</td><td>Key efficacy findings</td><td>Key safety findings</td><td>Comments</td></tr>
<tr>
<td>Viceconte N (2013)[5]

Case series
UK recruitment period: 2006-2010
Study population: patients undergoing post-procedural OCT examination after stent implantation (with 2 different stenting strategies) in coronary bifurcation lesion.
n = 41 (45 bifurcations)
Age: 67.8 years
Sex: 83% male

Technique: TD-OCT in 27 patients (Light Lab Imaging system) and FD-OCT in 14 patients (St Jude) was performed by non-occlusive technique to assess strut apposition immediately after drug-eluting stent implantation (PCI) across 4 segments inside the bifurcation. 30 bifurcations were treated with 1 stent and 15 received 2 stents. OCT pullbacks were performed in the main vessel.

Follow-up: 415 days (mean)

Conflict of interest/source of funding: study grant provided by Medtronic, StJude LightLab, Abbott, and Biosensors sponsored live transmissions</td>
<td>Number of patients analysed: 41 (54 bifurcations)

Strut malapposition

Strut malapposition was significantly more frequent in the half bifurcation facing the side-branch (SB) ostium (42.9%) than in the proximal segment of the bifurcation (11.8%), half bifurcation opposite the SB (6.7%), or the distal segment (5.7%) (all p<0.0001).

Comparison of 1 stent versus 2 stent techniques
Lesions (n = 15) treated with stenting of both main vessel (MV) and SB had a total higher rate of malapposition than those (n = 30) treated with stenting of the MV only (17.6% vs. 9.5%; p=0.0014).

Comparison of FD-OCT versus TD-OCT

In MV group, lesions treated with FD-OCT-guided stent implantation (n = 13) presented a lower rate of malapposition than those treated with conventional angiographic-guided stent implantation (n = 17) (7.1% vs. 17.5%; p=0.005).

Clinical outcomes
<table>
<tr><td></td><td>1 stent technique % (n)</td><td>2 stent technique % (n)</td><td>p value</td></tr>
<tr><td>TVR</td><td>13 (4/30)</td><td>7 (1/15)</td><td>0.65</td></tr>
<tr><td>Stent thrombosis</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Deaths</td><td>0</td><td>13 (2/15) (non-cardiac)</td><td>0.11</td></tr>
</table>
</td>
<td>None presented</td>
<td>.
- Clinical assessment done at 9 months.

Study design issues:
- Small prospective study.
- 26 patients had stenting on main vessel (MV) only and stenting of both MV and side branch was done in 15.
- Lack of randomisation between 1 stent and 2 stent strategies.
- 70% had elective procedures due to stable angina.
- Technique of treatment changed during study period.
- Different stent types were used.
- Analysis was limited to MV OCT pullback.
- All bifurcation lesions were classified by the Medina classification based on the presence/absence of >50% stenosis in the proximal and distal main vessel and the side branch ostium.</td>
</tr>
</table>

Abbreviations used: ACS, acute coronary syndrome; FD-OCT, frequency-domain optical coherence tomography; FFR, fractional flow reserve; PCI, percutaneous coronary intervention			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Stefano G (2011) [6] **Case series** USA Recruitment period: 2010 Study population: patients undergoing interventional coronary procedures n = **15 patients (19 target moderate stenoses)** Age: 69 years Sex: 64% male Patient selection criteria: patients undergoing both FD-OCT and FFR and with target stenoses classed as moderate (40-70% stenosis) by angiography were included. Technique: FD-OCT was performed with the C7 XR system (LightLab, St Jude Medical) Follow-up: **Not applicable** Conflict of interest/source of funding: Dr Costa is on the Speaker Bureau and is a consultant for BSC, Sanofi/Aventis, Eli Lilly, and Medtronic and is on the Speaker Bureau and a member of the Scientific Advisory Board for Abbott, Cordis, St Jude Medical and Scitech. Dr Bezerra reports receiving honoraria/research grants from St Jude Medical.	Number of patients analysed: **14 (18 target moderate stenoses)** **Procedural outcomes** OCT provided optimal visualisation in 95% (18/19) of the target segments. **Clinical decision making** FD-OCT data were used in decision-making in 71.4% (10/14) patients. 3 patients were noted to have angiographic tandem lesions. In these patients FD-OCT was useful in defining which lesion to treat. Of 6 patients with FFR >0.80 and a clinical presentation of ACS, FD-OCT ruled out plaque rupture, erosion and thrombosis to help guide decisions to defer PCI. 1 patient with FFR >0.80 underwent PCI with FD-OCT data and clinical information guiding the decision. FFR was used for decision-making in all patients.	FD-OCT was performed in all attempted cases without complication.	**Follow-up issues:** • One patient was excluded from this report due to uninterpretable FD-OCT data. **Study design issues**: • OCT images were analysed by two independent investigators who were blinded to FFR values. Where there was discordance between observers, a consensus reading was obtained by a third senior expert • Fractional flow reserve employs a sensor on the tip of a catheter to measure intravascular pressure differences across a coronary artery stenosis to determine the likelihood that the stenosis impedes oxygen delivery to the heart muscle. **Other issues**: • The authors state that FD-OCT had been used routinely at their centre since May 2010, and that patients were recruited from September to November 2010. This may suggest some inexperience with the procedure that could bias practitioners towards using FFR to guide decision-making.

<table>
<tr><td colspan="4">Abbreviations used: IVUS, intravascular ultrasound; MI, myocardial infarction; MLA, minimal lumen area; MLD, minimal lumen diameter; OCT, optical coherence tomography; PCI, percutaneous coronary intervention, TD-OCT, time-domain optical coherence tomography.</td></tr>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>
Yamaguchi, T (2008)[7]
Comparative study
Japan
Recruitment period: 2004-2005
Study population: patients undergoing coronary angiography and/or PCI
n=76
Age: 63.3 years
Sex: 88% male

Patient selection criteria:
Inclusion criteria: patients aged 20-75, not pregnant and protected against pregnancy; undergoing angiography and/or PCI; stenosis <99% and length <20mm.

Exclusion criteria: acute MI; ejection fraction <30%, target lesion in an ostium, a bifurcation, a left main coronary artery, or a vessel with thrombus or severe calcification.

Technique: TD-OCT was performed with an M2 OCT system (LightLab Imaging). The occlusion balloon technique was used.
Follow-up: not applicable
Conflict of interest/source of funding: this study was supported by a grant from Goodman Corp (occlusion balloon manufacturers).
</td>
<td>
Number of patients analysed: 76 patients: 110 acquisitions

<i>Procedural outcomes</i>
Success rates
<table>
<tr><th></th><th>OCT n (%)</th><th>IVUS n (%)</th><th>p value</th></tr>
<tr><td>Overall (n=110)</td><td>107 (97.3%)</td><td>104 (94.5%)</td><td>0.307</td></tr>
<tr><td>Diagnostic catheterisation (n=36)</td><td>36 (100%)</td><td>36 (100%)</td><td>1</td></tr>
<tr><td>Before PCI (n=40)</td><td>37 (92.5%)</td><td>34 (85.0%)</td><td>0.284</td></tr>
<tr><td>After PCI (n=34)</td><td>34 (100%)</td><td>34 (100%)</td><td>1</td></tr>
</table>
The OCT image wire was able to cross 5 out of 6 tight stenoses that the IVUS catheter could not cross.

Image quality n=98 matched acquisitions
<table>
<tr><th></th><th colspan="2">Lumen border</th><th colspan="2">Vessel border</th></tr>
<tr><th></th><th>OCT</th><th>IVUS</th><th>OCT</th><th>IVUS</th></tr>
<tr><td>Good</td><td>88</td><td>81</td><td>5</td><td>55</td></tr>
<tr><td>Fair</td><td>4</td><td>0</td><td>7</td><td>7</td></tr>
<tr><td>Poor</td><td>6</td><td>17</td><td>86</td><td>36</td></tr>
<tr><td>p value</td><td colspan="2">0.037</td><td colspan="2"><0.0001</td></tr>
</table>
<i>IVUS and OCT measurements</i>
MLD and MLA measured by OCT were significantly correlated with those measured by IVUS (r=0.91; p<0.0001). However, both measurements were significantly smaller by OCT (MLD 0.1mm, p=0.008; MLA 0.4mm^2, p<0.0001).
</td>
<td>
Some transient events, such as chest discomfort, bradycardia or tachycardia and ST-T changes on electrocardiogram, were observed during OCT or IVUS imaging all of which resolved immediately after the procedure.

Neither haemodynamic instability nor ventricular tachyarrhythmia was observed.

There were no major complications including MI, emergency revascularisation, or death.

There were no acute procedural complications including acute vessel occlusion, dissection, thrombus formation, embolism or vasospasm.
</td>
<td>
Study design issues:
• Multicentre study.
• Main study findings (not reported here) are the differences in measurements taken on OCT images versus IVUS images.
• The study was not designed to look at clinical outcomes.
• The study reveals a significant difference in absolute values in measurements taken using OCT imaging compared with measurements taken using IVUS. However, neither technique can claim to be the Gold Standard. The true values of the measurements are unknown.
</td>
</tr>
</table>

<table>
<tr><td colspan="4">Abbreviations used: FD-OCT, frequency-domain optical coherence tomography; IVUS, intravascular ultrasound; MLA, minimal lumen area; MLD, minimal lumen diameter; NIH, neointimal hyperplasia; OCT, optical coherence tomography; RLA, reference lumen area; RLD, reference lumen diameter; TD-OCT, time-domain optical coherence tomography</td></tr>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Bezerra HG (2013)[8]

Comparative study
US, Italy, Japan, Latvia (analysis completed in US)
Recruitment period: not stated
Study population: patients enrolled in various (unspecified) clinical trials. Indications for using both imaging modalities varied by individual study protocol.
Matched OCT and IVUS images of the native coronary artery immediately post-procedure and 6-12 months after stenting were included.
n = 187 patients: 454 pullbacks (227 IVUS vs. 100 FD-OCT and 127 TD-OCT)
Age: 65.1 years
Sex: 77.5% male

Patient selection criteria:

Inclusion criteria: completeness of the pullback; good image quality (>70% of analysable frames in both modalities).

Exclusion criteria: bifurcation segments with side branch occupying 45^o of the cross-section; failure to match OCT and IVUS pullbacks for the same</td>
<td>Number of matched pullbacks analysed: 227 (227 IVUS, 100 FD-OCT, 127 TD-OCT)

<i>Coronary artery disease assessment</i>
The results showed equivalence between FD-OCT and IVUS in determining reference lumen dimensions. FD-OCT detected smaller MLA and higher %stenosis than IVUS
<table>
<tr><th></th><th>Difference (mm, mm^2 for area) FD-OCT-IVUS (n=56)</th><th>p value</th></tr>
<tr><td>RLA</td><td>-0.19</td><td>0.29</td></tr>
<tr><td>RLD</td><td>-0.05</td><td>0.23</td></tr>
<tr><td>MLA</td><td>-0.99</td><td><0.001</td></tr>
<tr><td>MLD</td><td>-0.37</td><td><0.001</td></tr>
<tr><td>Area stenosis %</td><td>13.51</td><td><0.001</td></tr>
<tr><td>Diameter stenosis %</td><td>12.74</td><td><0.001</td></tr>
</table>
<i>Assessment of stented vessels</i>
Both TD-OCT and FD-OCT were more sensitive for detection of stent malapposition, NIH, and intra-stent tissue protrusion. TD-OCT systematically underestimated reference vessel-dimensions.

<i>Post-PCI assessment of stented vessels</i>
<table>
<tr><th></th><th>Difference (mm, mm^2 for area) FD-OCT-IVUS (n=26)</th><th>p value</th></tr>
<tr><td>RLA</td><td>-0.31</td><td>0.33</td></tr>
<tr><td>RLD</td><td>-0.07</td><td>0.28</td></tr>
<tr><td colspan="3">In-stent lumen area</td></tr>
<tr><td>Mean</td><td>-0.01</td><td>0.95</td></tr>
<tr><td>Min</td><td>0.14</td><td>0.54</td></tr>
<tr><td>Max</td><td>-0.27</td><td>0.38</td></tr>
<tr><td colspan="3">Stent area</td></tr>
<tr><td>Mean</td><td>-0.50</td><td>0.002</td></tr>
<tr><td>Min</td><td>-0.13</td><td>0.57</td></tr>
<tr><td>Max</td><td>-1.46</td><td>0.005</td></tr>
<tr><td>Protruding area</td><td>0.16</td><td><0.001</td></tr>
<tr><td>Malapposition area</td><td>0.24</td><td>0.017</td></tr>
</table>
</td>
<td>None reported</td>
<td>Study design issues:
• Protocols for image acquisition may have been different between centres.
• Intrinsic differences between the imaging methods mean exactly the same cross-section of each vessel may not have been identified for all comparisons. This may explain some of the differences observed between measurements.
• Neither IVUS nor OCT can claim to be the Gold Standard. The true values of the measurements are unknown.</td>
</tr>
</table>

<table>
<tr><td colspan="4">Abbreviations used: IVUS, intravascular ultrasound; MI, myocardial infarction; MLA, minimal lumen area; MLD, minimal lumen diameter; OCT, optical coherence tomography; PCI, percutaneous coronary intervention, TD-OCT, time-domain optical coherence tomography.</td></tr>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>patient/time point.

Technique: OCT imaging was performed using two different systems: TD-OCT (M2CV Imaging System, LightLab Imaging) and FD-OCT (C7XR Imaging System, LightLab Imaging). TD-OCT was performed using the occlusive technique.

Follow-up: **not applicable**

Conflict of interest/source of funding: 4 authors have received consulting fees from St Jude Medical. 1 has also received consulting fees from Boston Scientific and Volcano. 1 author has received honoraria from St Jude Medical. 2 authors have received research grants from St Jude Medical. 1 author has additionally received grant support from Medtronic, Scitech, Cordis, Boston Scientific and Abbott Vascular.</td>
<td>***Follow-up assessment of stented vessels***
<table>
<tr><th></th><th>Difference (mm, mm^2 for area) FD-OCT - IVUS (n=18)</th><th>p value</th><th>Difference (mm, mm^2 for area) TD-OCT-IVUS (n=127)</th><th>p value</th></tr>
<tr><td>RLA</td><td>0.34</td><td>0.07</td><td>-0.67</td><td><0.001</td></tr>
<tr><td>RLD</td><td>0.08</td><td>0.09</td><td>-0.16</td><td><0.001</td></tr>
<tr><td colspan="3">In-stent lumen area</td><td></td><td></td></tr>
<tr><td>Mean</td><td>-0.61</td><td>0.005</td><td>-0.72</td><td><0.001</td></tr>
<tr><td>Min</td><td>-1.00</td><td><0.001</td><td>-0.95</td><td><0.001</td></tr>
<tr><td>Max</td><td>0.04</td><td>0.93</td><td>-0.55</td><td><0.001</td></tr>
<tr><td colspan="3">Stent area</td><td></td><td></td></tr>
<tr><td>Mean</td><td>-0.04</td><td>0.85</td><td>0.07</td><td>0.17</td></tr>
<tr><td>Min</td><td>-0.23</td><td>0.22</td><td>0.02</td><td>0.69</td></tr>
<tr><td>Max</td><td>0.18</td><td>0.66</td><td>-0.15</td><td>0.099</td></tr>
<tr><td>NIH area</td><td>0.63</td><td><0.001</td><td>0.80</td><td><0.001</td></tr>
<tr><td>Stenosis (%)</td><td>7.87</td><td><0.001</td><td>10.32</td><td><0.001</td></tr>
<tr><td>Malapposition area</td><td>0.04</td><td>0.01</td><td>0.00</td><td>0.96</td></tr>
</table>
</td>
<td></td>
<td></td>
</tr>
</table>

<table>
<tr><td colspan="4">Abbreviations used: FFR, fractional flow reserve; MACE, major adverse cardiac events; MLA, minimal lumen area; MLD, minimal lumen diameter; NPV, negative predictive value; OCT, optical coherence tomography; PPV, positive predictive value; TD-OCT time-domain optical coherence tomography, TVR, target vessel revascularisation.</td></tr>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Radu MD (2013)[9]

Case series
Denmark, Netherlands, Switzerland
Recruitment period: 2008-2010
Study population: patients from the Copenhagen OCT registry and from the OCT substudy of the RESOLUTE all-comers trial.
n = 57 patients: 63 coronary lesions
Age: 63 years
Sex: 75% male

Patient selection criteria: inclusion criteria: lesions exhibiting edge dissections as assessed by OCT after stent implantation.

Technique: TD-OCT or FD OCT imaging with occlusive and non-occlusive techniques following drug-eluting stent implantation, LightLab/St Jude system (M2, M3, C7) used.
Follow-up: 1 year

Conflict of interest/source of funding: 1 author received consulting fees from Abbott, Boston Scientific, Biosensors, Cordis and Medtronic. Others have no conflicts of interest.</td>
<td>Number of patients analysed: 56 (62 lesions)
OCT detected edge dissections
35% (20/56) patients with 21 lesions showed 22 OCT non-flow limiting edge dissections. 9% (2/22) edge dissections were angiographically visible (as type A haziness and located in same vessel separated by 2 mm). Flaps were found in 96% (21/22) of dissections. The median longitudinal dissection length was 2.9 mm, whereas the circumferential and axial extensions amounted to 1.2 mm and 0.6 mm, respectively. Dissections extended into the media and adventitia in 7 (33%) and 4 (20%) dissections, respectively. 18 (82%) OCT-detected edge dissections were also evaluated with intravascular ultrasound, which identified nine (50%) of these OCT-detected dissections.
Healing response
90% (20/22) edge dissections were completely healed on OCT at 1 year follow-up. The 2 cases that did not heal had the longest flaps (2.81 mm and 2.42 mm) at baseline.
Morphology results
<table>
<tr><th>OCT (n=22)
Reference vessel segment</th><th>Baseline</th><th>1-year follow-up</th><th>p value</th></tr>
<tr><td>Lumen area, mm2</td><td>5.35±1.73</td><td>5.58±1.72</td><td>0.203</td></tr>
<tr><td>Lumen diameter, mm</td><td>2.58±0.42</td><td>2.64±0.38</td><td>0.174</td></tr>
</table>

Clinical outcomes
All patients except 1 received dual antiplatelet therapy during 1-year follow-up period. No deaths, MIs, stent thrombosis or target lesion revascularisation occurred up to 1 year. 2 patients with persistent edge dissections at 1-year follow-up were free of MACE up to 3 years after the index procedure.</td>
<td>
At 1-year imaging procedure 1 patient had a clinically driven TVR.</td>
<td>Follow-up:
1 patient (1 lesion) with no serially analysable edge dissection was excluded.
Study design issues:
Small observational study.
Serial data from 2 studies (Copenhagen OCT registry and the OCT substudy of the RESOLUTE all-comers trial) included.
The dissection was graded according to the National Heart Lung and Blood Institute classification.
Angiograms were assessed by 3 independent cardiologists for presence of edge dissections.
Edge dissections were defined as tears of the luminal surface in the 5 mm segment proximal and distal to the stent and categorised as flaps, cavities, double lumen dissections or fissures.
OCT analyses performed every 0.5 mm at baseline and 1 year.
Clinical outcomes were assessed by 2 independent observers blinded to imaging results for the Copenhagen registry and for the RESOLUTE trial by a clinical events adjudication committee.</td>
</tr>
</table>

Abbreviations used: BP, blood pressure; FD-OCT, frequency-domain optical coherence tomography; IVUS, intravascular ultrasound; OCT, optical coherence tomography; TD-OCT, time-domain OCT			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Dobarro, D (2010)[10]; Kim, J-S (2008)[11]; Park, C-B (2012)[12]; Seo, Y-S (2008)[13]; Wiyono, S (2012)[14] **5 case reports** 3 x Republic of Korea; 1 x Spain; 1 x The Netherlands Study population: 1 x evaluation of right coronary artery; 4 x previous history of PCI admitted for follow-up. n = **5** Age: 64-77 years (range) Sex: 2 male; 3 female Technique: 3 used occlusion TD-OCT, one used TD-OCT and did not state whether or not it was the occlusive or non-occlusive technique. One paper reports use of FD-OCT. Follow-up: **not applicable** Conflict of interest/source of funding: none	Number of patients analysed: **5 patients**	One patient complained of chest pain during withdrawal of the OCT wire, which was caused by vessel-spasm. ST-segment elevation was registered on ECG. This was completely resolved with use of intracoronary nitrate. In 3 cases, multiple thrombi formation occurred during the OCT procedure. These were treated with 24-hour intravenous heparin in 1 patient and thrombus aspiration in 2 patients. All 3 patients had no significant deterioration in their condition, with 2 of the patients reported as being discharged and recovering uneventfully. In 1 patient a large coronary perforation occurred during OCT, leading to BP depression and loss of consciousness. Attempts to seal the perforation in the catheterisation lab failed and the patient was transferred to the operating room for surgical repair. Arterial grafting was performed but the patient died after cardiac arrest 7 days after surgery.	**Study design issues**: • In 2 cases, IVUS had been performed immediately before OCT. • Just 1 of these serious complications arose in a FD-OCT case (thrombus formation) with the other 4 occurring with use of TD-OCT.

Efficacy

A retrospective case series compared 335 matched pairs of patients undergoing percutaneous coronary intervention (PCI) with either angiographic guidance only or angiographic and frequency-domain optical coherence tomography (FD-OCT) guidance. FD-OCT led to additional interventions (further stenting and additional balloon dilation) in 35% (116) of patients. Patients who had PCI with FD-OCT guidance were less likely than those who had PCI with angiographic guidance alone to have a cardiac death or myocardial infarction (MI) over a follow-up period of 1 year (odds ratio 0.49; 95% confidence interval 0.25 to 0.96; p=0.037, adjusted for all covariates associated with the OCT group)[1].

In a randomised controlled trial (RCT) comparing FD-OCT against intravascular ultrasound (IVUS) for PCI optimisation in 70 patients, there was inferior stent expansion, both focal (65% versus 80%, p=0.002) and diffuse (84% versus 99%, p=0.003) when FD-OCT had been used. PCI guided by FD-OCT also showed a significant increase in residual stent-edge plaque burden compared against IVUS (51% versus 42% p<0.001). There were no significant differences in stent apposition[2].

A case series of 90 patients undergoing 114 FD-OCT image acquisitions reported that, of the 40 patients in whom OCT was used to evaluate ambiguous or intermediate lesions, 24 were treated with PCI and 16 had PCI deferred. None of the patients for whom PCI was deferred experienced a coronary event. All these patients were symptom free at an average follow-up of 4.6 months. Additional interventions were prompted in 24 of 74 patients who had a stent assessed with OCT[3].

A case series of 14 patients who underwent both fractional flow reserve (FFR) or FD-OCT investigations when presenting with moderate stenosis (according to angiography) reported use of FD-OCT to aid decision-making in 71% (10/14) of patients. In 3 patients with tandem lesions, FD-OCT was useful in defining which lesion to treat. In 6 patients with acute coronary syndromes (ACS) and FFR>0.80, FD-OCT supported the decision to defer PCI. In 1 patient with FFR>0.80, FD-OCT data were used by the treating physician in their decision to use PCI[6].

In a comparative study of 76 patients who underwent imaging by both OCT and IVUS, the OCT image wire was able to cross 5 out of 6 tight stenoses that the IVUS catheter could not cross[7].

Diagnostic outcomes

In the RCT comparing FD-OCT (35 patients) with IVUS (35 patients) for PCI optimisation, OCT was judged to be significantly worse for visualising the vessel border. Vessel border visibility at the minimum lumen area (MLA) site was good in 9% (3/35) of patients when visualised by OCT, compared with 94% (33/35) of patients when visualised by IVUS ($p<0.001$)[2].

In a comparative study that examined 56 matched FD-OCT and IVUS assessments of coronary artery disease, FD-OCT detected smaller MLA and higher percentage stenosis than IVUS ($p<0.001$). In 26 matched OCT and IVUS assessments of stented vessels, both time-domain optical coherence tomography (TD-OCT) and FD-OCT were more sensitive than IVUS for detection of stent malapposition, neointimal hyperplasia and intra-stent protrusion. TD-OCT reported systematically smaller reference vessel dimensions[8].

In the comparative study examining TD-OCT and IVUS in the same 98 vessels (from 76 patients), visibility of the vessel border was judged to be poor in 88% (86/98) of TD-OCT acquisitions and 37% (36/98) of IVUS acquisitions ($p<0.0001$). However, this study also found that TD-OCT was significantly better for visualising the lumen border ($p=0.037$). Measurements by TD-OCT were significantly correlated with those from IVUS, although they were significantly smaller[7].

In a case series of 53 patients with 69 non-significant coronary plaques, plaque characteristics recognised by TD-OCT imaging were shown to be significantly correlated with plaque progression. These were intimal laceration ($p<0.001$), microchannel ($p<0.001$), thin cap fibroatheroma ($p<0.001$), presence of macrophages ($p=0.001$) and thrombus (0.002). This suggests that plaque characteristics on OCT images could be used to inform clinical decision-making when considering whether a particular plaque poses a risk to a patient[5].

A case series of 41 patients with 45 coronary bifurcation lesions, assessed after stenting with OCT, reported that strut malapposition was significantly more frequent in the half bifurcation facing the side-branch (SB) ostium (42.9%) than in the proximal segment of the bifurcation (11.8%), half bifurcation opposite the SB (6.7%), or the distal segment (5.7%) (all $p<0.0001$). Lesions ($n=15$) treated with stenting of both main vessel (MV) and SB had a total higher rate of malapposition than those ($n=30$) treated with stenting of the MV only (17.6% versus 9.5%; $p=0.0014$). In the latter group, lesions treated with FD-OCT-guided stent implantation ($n=13$) presented a lower rate of malapposition than those treated with conventional angiographic-guided stent implantation ($n=17$) (7.1% versus 17.5%; $p=0.005$)[5].

A case series of 57 patients with 63 lesions, assessed with OCT following drug-eluting stent implantation reported that 22 non-flow-limiting edge dissections in 21 lesions (20 patients) were identified by OCT; only 2 (9%) were angiographically visible. Ninety per cent (20/22) of edge dissections were completely healed on OCT at 1-year follow-up. No deaths, MIs, stent thrombosis or target lesion revascularisation occurred up to 1 year[9].

Safety

A large coronary perforation occurred (no further details of cause available) during optical coherence tomography (OCT) imaging in 1 patient presented in a case report, leading to reduced blood pressure and loss of consciousness. Surgical repair was done but the patient died of cardiac arrest after 7 days[12].

Major complications including 5 ventricular fibrillations (3 out of 256 during occlusive imaging and 2 out of 212 during non-occlusive imaging), 1 dissection, 3 air embolisms and 1 mechanical device failure were reported in a case series of 468 patients during time-domain OCT (TD-OCT) imaging. There was no significant difference in occurrence with the occlusive or the non-occlusive technique. A range of self-limiting events were also seen during TD-OCT imaging. The most common was chest pain (48%), which was significantly more common when the occlusive technique was employed (70% [180/256] compared with 21% [45/212], $p<0.001$). Widening QRS or ST depression and ST elevation were also more common in occlusive TD-OCT than in non-occlusive TD-OCT (54% [139/256] versus 25% [53/212], $p<0.001$; and 7% [18/256] versus 2% [4/212], $p=0.01$ respectively). Of these events, just under 97% were immediately resolved, 3% required specific treatment but resolved before leaving the catheterisation laboratory, and less than 1% persisted beyond discharge from the laboratory and required ongoing clinical surveillance[4].

Multiple thrombi were reported during OCT imaging in 3 patients presented in case reports. These formed during OCT imaging in the left anterior descending artery, causing total occlusion in 1 patient and subtotal occlusion in 2 others. The thrombi were treated with intravenous heparin in 1 patient and thrombus aspiration in 2 patients. All resolved with appropriate management and all patients recovered uneventfully[11,13,14].

A vessel-spasm during withdrawal of the OCT wire, causing chest pain and ST-segment elevation, was reported in a single case report. This completely resolved with an intracoronary injection of nitrate[10].

A transient vessel spasm that resolved spontaneously was reported in 1 patient in the case series of 90 patients undergoing 114 OCT image acquisitions. Ventricular ectopic beats were noted in 3 patients, but no ischaemic ECG changes or other major arrhythmias were observed[3].

Transient events such as chest discomfort, bradycardia and tachycardia, and ST-T changes on ECG were observed during TD-OCT or IVUS imaging in the study comparing TD-OCT and IVUS of the same target areas in 76 patients (110 acquisitions). All resolved immediately after the procedure. Neither haemodynamic instability nor ventricular tachyarrhythmia was observed. There were no major complications such as MI, emergency revascularisation or death. There were no acute procedural complications, including acute vessel occlusion, dissection, thrombus formation, embolism or vasospasm[7].

Validity and generalisability of the studies

- Just 1 study examined whether using OCT led to better clinical outcomes at 1-year follow-up[1]. All other studies were concerned with how useful OCT might be in clinical decision-making.
- Just 3 studies reported on clinical follow-up of patients who had undergone OCT. No study followed patients beyond a year post-procedure.
- There are likely to be significant differences in both the safety and efficacy of TD-OCT, with and without balloon occlusion, and FD-OCT. The balloon occlusion method has been superseded by the constant flush method for coronary work in this country.
- This overview presents 2 studies using TD-OCT with balloon occlusion, 1 study using non-occlusive TD-OCT, 1 using both occlusive and non-occlusive TD-OCT, 1 using occlusive TD-OCT and FD-OCT, and 4 studies using FD-OCT. The 5 case reports of safety events include 3 using TD-OCT with balloon occlusion, 1 using TD-OCT without stating whether occlusion was used or not, and 1 using FD-OCT.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Technology appraisals

- Guidance on the use of coronary artery stents. NICE technology appraisal guidance 71 (2003). Available from www.nice.org.uk/guidance/TA71

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Dr Saqib Chowdhary (British Cardiovascular Society); Professor Tony Gershlick (British Cardiovascular Society); Mr Robert Henderson (British Cardiovascular Society).

- Two specialist advisers perform this procedure regularly; 1 has performed it at least once.
- Two specialist advisers considered this procedure established practice and no longer new; 1 considered it to be definitely novel and of uncertain safety and efficacy.
- All 3 specialist advisers considered intravascular ultrasound (IVUS) to be the comparator for this procedure.
- Key efficacy outcomes include a change in diagnosis or management because of the results of optical coherence tomography (OCT) imaging, mentioned by 3 specialist advisers. Other examples include identifying culprit or non-culprit plaques in acute coronary syndrome (ACS), including plaque erosion that cannot be detected by other forms of in-vivo imaging; identifying intra-coronary or intra-stent thrombus; identifying dissections and complications after stenting; examining stent deformation and conformation; identifying modes of stent failure including neoatherogenesis; and documenting stent tissue coverage.
- Uncertainties and concerns about the efficacy of this procedure include questions about the prospective clinical relevance of certain OCT findings given the extremely high resolution of the imaging provided. Specifically, there were uncertainties around the thresholds for stent-related dissections or inappositions that would need further intervention; the patterns of incomplete tissue coverage that would predict high late stent thrombosis rates; and the paucity of long-term outcome data.
- The specialist advisers stated that limited instruction is needed by experienced interventional cardiologists to carry out OCT safely and effectively, but that training is needed to correctly interpret OCT images.

Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Issues for consideration by IPAC

- There is one ongoing trial. NCT01743274: Does Optical Coherence Tomography Optimise Results of Stenting (DOCTORS); Location: France; Type: RCT; Estimated enrolment: 230; Estimated study completion date: March 2014.

References

1. Prati F, Di VL, Biondi-Zoccai G et al. (2012) Angiography alone versus angiography plus optical coherence tomography to guide decision-making during percutaneous coronary intervention: The Centro per la Lotta contro l'Infarto-Optimisation of Percutaneous Coronary Intervention (CLI-OPCI) study. EuroIntervention.8 (7) (pp 823-829), 2012.Date of Publication: November 2012. 823-829.

2. Habara M, Nasu K, Terashima M et al. (2012) Impact of frequency-domain optical coherence tomography guidance for optimal coronary stent implantation in comparison with intravascular ultrasound guidance. Circulation: Cardiovascular Interventions 5:193-201.

3. Imola F, Mallus MT, Ramazzotti V et al. (2010) Safety and feasibility of frequency domain optical coherence tomography to guide decision making in percutaneous coronary intervention. Eurointervention 6:575-581.

4. Barlis P, Gonzalo N, Di MC et al. (2009) A multicentre evaluation of the safety of intracoronary optical coherence tomography. Eurointervention 5:90-95.

5. Viceconte N et al (2013). Immediate results of bifurcational stenting assessed with optical coherence tomography. Catheterization & Cardiovascular Interventions 81 (3) 519-528.

6. Stefano GT, Bezerra HG, Attizzani G et al. (2011) Utilization of frequency domain optical coherence tomography and fractional flow reserve to assess intermediate coronary artery stenoses: conciliating anatomic and physiologic information. The International Journal of Cardiovascular Imaging 27:299-308.

7. Yamaguchi T, Terashima M, Akasaka T et al. (2008) Safety and feasibility of an intravascular optical coherence tomography image wire system in the clinical setting. American Journal of Cardiology 101:562-567.

8. Bezerra H, Attizzani G, Sirbu V et al. (2013) Optical Coherence Tomography versus Intravascular Ultrasound to Evaluate Coronary Artery Disease and Percutaneous Coronary Intervention. JACC: Cardiovascular Interventions 6: 228-36.

9. Radu MD et al (2013). Natural history of optical coherence tomography-detected non-flow-limiting edge dissections following drug-eluting stent implantation. Eurointervention 2013. Dobarro D, Jimenez-Valero S, and Moreno R. (2010) Severe coronary spasm induced by OCT wire. There are no innocuous procedures. Journal of Invasive Cardiology 22:385

10. Kim J-S, Choi E-Y, Choi D et al. (2008) Catastrophic thrombus formation during optical coherence tomography. Circulation.118 (6) (pp e101-e102), 2008.Date of Publication: 05 Aug 2008. e101-e102.

11. Park CB, Joe BH, Hwang HJ et al. (23-2-2012) Coronary perforation during conventional time domain optical coherence tomography. International Journal of Cardiology 155:e14-e15.

12. Seo Y-S, Lee JM, Son JY et al. (2008) A newly developed stent thrombus related to optical coherence tomography. Korean Circulation Journal.38 (12) (pp 674-676), 2008.Date of Publication: December 2008. 674-676.

13. Wiyono SA, Van Beusekom HMM, Ligthart JM et al. (2012) Thrombotic complication during intracoronary imaging. Netherlands Heart Journal.20 (5) (pp 229-231), 2012.Date of Publication: May 2012. 229-231.

Appendix A: Additional papers on Optical Coherence Tomography to guide percutaneous coronary intervention

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	**Number of patients/follow-up**	**Direction of conclusions**	**Reasons for non-inclusion in table 2**
Abnousi F et al (2013). Variability in quantitative and qualitative analysis of intravascular ultrasound and frequency domain optical coherence tomography. Catheterization & Cardiovascular Interventions 82 (3) E192-E199.	n=14 226+/-2 stent cross-sections with IVUS and 232+/-2 stent cross-sections with FD-OCT	Despite varying levels of training, the increased resolution of FD-OCT compared to IVUS provides better detection and less variability in quantitative image analysis. On the contrary, this increased resolution not only increases the rate but also the variability of detection of qualitative image analysis, especially for beginner analysts.	Other studies provide outcomes that are more clinically relevant.
Adlam D, Hutchings D, and Channon KM. (2011) Optical coherence tomography-guided stenting of a large coronary aneurysm: images at implantation and at 6 months. Journal of Invasive Cardiology 23:168-169.	1	OCT was useful for guiding PCI in this patient.	A case-study. Clinical outcomes from larger studies available.
Alcock R, Yong AS, Yiannikas J et al. (2012) Optical coherence tomography-guided left main stem stenting: a new approach? Texas Heart Institute Journal 39:596-	1	OCT guidance of LMCA stenting is a straightforward and precise method that warrants further evaluation.	A case-study. Clinical outcomes from larger studies available.

597.			
Alegria-Barrero E, Foin N, Chan PH et al. (2012) Choosing the right cell: guidance with three-dimensional optical coherence tomography of bifurcational stenting. European heart journal cardiovascular Imaging 13:443-	2	High resolution intravascular imaging with OCT and 3D reconstruction has the unique ability to clearly identify the position of wire crossing during bifurcation stenting.	Case studies concerned primarily with 3D reconstruction of OCT images.
Alfonso F, Canales E, and Aleong G. (2009) Spontaneous coronary artery dissection: Diagnosis by optical coherence tomography. European Heart Journal.30 (3) (pp 385), 2009.Date of Publication: February 2009. 385-	1	OCT provided unique insights into the underlying substrate of the proximal restenosis unravelling a complicated plaque with associated thrombus.	A case-study. Clinical outcomes from larger studies available.
Alfonso F, Canales E, Dutary J et al. (2011) Coronary dissection healing patterns: from complete resolution to restenosis, insights from optical coherence tomography. Eurointervention 7:270-273.	1	The unique spatial resolution provided by OCT might be particularly valuable in the decision-making process involved in the management of patients suffering from this rare entity.	A case-study. Clinical outcomes from larger studies available.
Alfonso F, Dutary J, Paulo M et al. (2012) Combined use of optical coherence tomography and intravascular ultrasound imaging in patients undergoing coronary interventions for stent thrombosis. Heart 98:1213-1220	15	OCT provides unique insights on the underlying substrate of ST and may be used to optimise results in these challenging interventions. In this setting, OCT and IVUS have complementary diagnostic values.	Other studies provide outcomes that are more clinically relevant.
Alfonso F, Gonzalo N, and Hernandez R. (2011) A rare cause of late drug-eluting stent thrombosis unravelled by optical coherence tomography. Circulation:	1	The unique spatial resolution provided by OCT might be very useful to identify causative substrates at the DES edge and therefore particularly	A case-study. Clinical outcomes from larger studies available.

Cardiovascular Interventions.4 (4) (pp 399-400), 2011.Date of Publication: August 2011. 399-400.		valuable in the clinical decision-making process.	
Alfonso F, Paulo M, Gonzalo N et al. (20-3-2012) Diagnosis of spontaneous coronary artery dissection by optical coherence tomography. Journal of the American College of Cardiology 59:1073-1079.	17	OCT provides unique insights in patients with spontaneous coronary artery dissection that allow an early diagnosis and adequate management. Most of these findings are undetectable by angiography.	Other studies provide outcomes that are more clinically relevant.
Amabile N et al (2013). Very late stent thrombosis related to incomplete neointimal coverage or neoatherosclerotic plaque rupture identified by optical coherence tomography imaging. Eur Heart J Cardiovasc Imaging	n=2139 ACS patients, OCT	20 patients with very late stent thrombosis (VLST), 10 with evidence of in-stent neoatheroma (ISNA) were identified. ISNA is frequent in patients with VLST. All the ISNA lesions were treated through initial thrombectomy followed by redo stenting in 9 patients. Results suggest that OCT imaging is helpful in identifying the underlying mechanisms of VLST and, therefore, in the clinical decision-making process.	These efficacy findings are reported in bigger studies with larger numbers and better methodology.
Attizzani GF, Patricio L, and Bezerra HG. (2013) Optical coherence tomography assessment of calcified plaque modification after rotational atherectomy. Catheterization & Cardiovascular Interventions 81:558-561.	1	OCT revealed unique insights into calcified coronary plaque modification.	A case-study. Clinical outcomes from larger studies available.
Barlis P, Dimopoulos K, Tanigawa J et al. (28-5-2010) Quantitative	30	This supports the validity of OCT as a clinical and research	These efficacy findings are reported in

analysis of intracoronary optical coherence tomography measurements of stent strut apposition and tissue coverage. International Journal of Cardiology 141:151-156.		tool in the setting of intracoronary stent imaging.	bigger studies with larger patient numbers. Other studies contain more clinical outcomes.
Barlis P, Serruys PW, Gonzalo N et al. (2008) Assessment of Culprit and Remote Coronary Narrowings Using Optical Coherence Tomography With Long-Term Outcomes. American Journal of Cardiology.102 (4) (pp 391-395), 2008.Date of Publication: 15 Aug 2008. 391-395.	23	This study showed that OCT can be safely applied to image beyond the culprit lesion and can detect in vivo morphologic features associated with plaque vulnerability using retrospective pathologic examination.	These efficacy findings are reported in bigger studies with larger n numbers and better methodology.
Belkacemi A et al (2013). Diagnostic accuracy of optical coherence tomography parameters in predicting in-stent hemodynamic severe coronary lesions: Validation against fractional flow reserve. International Journal of Cardiology 168 (4) 4209-4213.	n=27 OCT and FFR	With OCT, a good diagnostic efficiency can be achieved in identifying coronary severity in in-stent lesions in a per-group analysis. This provides an extra dimension, next to morphological information, when acquiring OCT images in scientific studies. OCT seems limited in a per-patient clinical decision making process due to reasonable but limited sensitivity and specificity in predicting coronary severity.	Other studies provide outcomes that are more clinically relevant.
Bezerra HG et al (2013). Three-dimensional imaging of fibrous cap by frequency-domain optical coherence tomography. Catheterization & Cardiovascular Interventions 81 (3) 547-	n=2	Illustrate the importance of three-dimensional volumetric quantification of the FC capitalizing on the properties of frequency-domain	Other studies provide outcomes that are more clinically relevant.

549.		iOCT.	
Bouki KP, Chatzopoulos DN, Katsafados MG et al. (12-11-2009) Late acquired stent malapposition detected by optical coherence tomography examination. International Journal of Cardiology 137:e77-e78.	1	OCT was used to aid the successful diagnosis and treatment of this patient.	A case-study. Clinical outcomes from larger studies available.
Bouki KP, Chatzopoulos DN, Sakkali EK et al. (2011) Visualization of coronary plaque rupture using optical coherence tomography. Hjc Hellenic Journal of Cardiology 52:168-170.	1	OCT was used to evaluate the culprit lesion morphology in a patient with acute myocardial infarction and to confirm good stent apposition.	A case-study. Clinical outcomes from larger studies available.
Bouma BE, Tearney GJ, Yabushita H et al. (2003) Evaluation of intracoronary stenting by intravascular optical coherence tomography. Heart 89:317-320.	39	Intracoronary OCT for monitoring stent deployment is feasible and provides superior contrast and resolution of arterial pathology than IVUS.	Older and smaller paper with safety findings covered by bigger newer papers and more clinically relevant efficacy findings presented elsewhere.
Bozkurt A et al (2013). A new diagnostic method for woven coronary artery: Optical coherence tomography. Herz.38 (4) (pp 435-438), 2013.Date of Publication: June 2013. (4) 435-438.	n=1 Case report	OCT used for the definitive diagnosis and appropriate treatment of woven coronary artery.	A case-study with no additional efficacy or safety information.
Brugaletta S, Gomez-Lara J, Bruining N et al. (20-7-2012) Head to head comparison of optical coherence tomography, intravascular ultrasound echogenicity and virtual histology for the detection of changes in polymeric struts over time: insights from the ABSORB trial.	35	OCT is able to detect changes in the scaffold struts, although the correlation between OCT detected changes IVUS, echo and VH was small.	These efficacy findings are reported in bigger studies with larger n numbers and better methodology.

Eurointervention 8:352-358.			
Buellesfeld L, Lim V, Gerckens U et al. (2005) Comparative endoluminal visualization of TAXUS crush-stenting at 9 months follow-up by intravascular ultrasound and optical coherence tomography. Zeitschrift fur Kardiologie 94:690-694.	1	OCT provided superior imaging quality and provided new insights into the stent performance at the open bifurcation site.	A case-study. Clinical outcomes from larger studies available.
Burris N, Schwartz K, Tang CM et al. (2007) Catheter-based infrared light scanner as a tool to assess conduit quality in coronary artery bypass surgery. Journal of Thoracic & Cardiovascular Surgery 133:419-427.	50	OCT imaging provides an accurate, real-time and reproducible means for assessing saphenous vein graft and radial artery graft bypass conduits. As a quality assurance tool, this technology might afford a more objective basis for conduit selection.	Efficacy outcomes more relevant to clinical practice were present in other studies.
Cao HM, Jiang JF, Deng B et al. (2010) Evaluation of myocardial bridges with optical coherence tomography. Journal of International Medical Research 38:681-685.	12	The morphological and intimal structure characteristics of MBs can be observed clearly with OCT.	Other studies contain outcomes that are more relevant to clinical practice.
Capodanno D, Prati F, Pawlowsky T et al. (2009) Comparison of optical coherence tomography and intravascular ultrasound for the assessment of in-stent tissue coverage after stent implantation. Eurointervention 5:538-543.	20	OCT can quantify in-stent coverage and detect strut healing with high reproducibility. IVUS tends to underestimate the percentage of in-stent tissue coverage as compared to OCT.	Other studies contain outcomes that are more relevant to clinical practice.
Carrizo S, Salinas P, Jimenez-Valero S et al. (2013) Utility of optical coherence tomography to assess a hazy intracoronary image after percutaneous coronary	1	This case illustrates the ability of OCT for accurate diagnosis of an intracoronary post-angioplasty that had an uncertain hazy image, and its	A case-study. Clinical outcomes from larger studies available.

intervention. Sunhwangi 43:44-47.		usefulness as a guide for therapeutic strategy.	
Cho JM, Sohn IS, Kim CJ et al. (2011) Vulnerable plaque inside stent. Jacc: Cardiovascular Imaging 4:430-431.	1	OCT used as a tool to aid in the management of this patient.	A case-study. Clinical outcomes from larger studies available.
Dato I et al (2013). Multiple coronary plaque ruptures in a patient with a recent ST-elevation acute myocardial infarction causing recurrent coronary instability. Journal of Cardiovascular Medicine.14 (9) (pp 681-682), 2013.Date of Publication: September 2013. (9) 681-682.	n=1 case report	Case of multiple coronary instability in a patient with anterior STEMI where OCT has tailored an optimal diagnosis and treatment.	A case-study with no additional efficacy or safety information.
Diaz-Sandoval LJ, Bouma BE, Tearney GJ et al. (2005) Optical coherence tomography as a tool for percutaneous coronary interventions. Catheterization & Cardiovascular Interventions 65:492-496.	10	OCT provides cross-sectional images of tissue in situ at high resolution, rendering detailed structural information.	This paper is older and smaller and others reporting similar efficacy findings. Other studies contain outcomes that are more relevant to clinical practice.
Diletti R, Garcia-Garcia HM, Gomez-Lara J et al. (2011) Assessment of coronary atherosclerosis progression and regression at bifurcations using combined IVUS and OCT. Jacc: Cardiovascular Imaging 4:774-780.	24	The combined use of IVUS-VH and OCT is a reliable tool to serially assess plaque progression and regression, and in the present study it was demonstrated to be safe and feasible.	Other studies contain outcomes that are more relevant to clinical practice.
Fedele S, Biondi-Zoccai G, Kwiatkowski P et al. (15-10-2012) Reproducibility of coronary optical coherence tomography for lumen and length	25	FD-OCT showed excellent reproducibility, with low intraobserver, interobserver and interpullback variability for both	Other studies contain outcomes that are more relevant to clinical practice.

measurements in humans (The CLI-VAR [Centro per la Lotta contro l'Infarto-VARiability] study). American Journal of Cardiology 110:1106-1112.		lumen area and lesion length measurements in humans.	
Fujino, Y et al (2013). Frequency-domain optical coherence tomography assessment of unprotected left main coronary artery disease - A comparison with intravascular ultrasound. Catheterization and Cardiovascular Interventions.82 (3) (pp E173-E183), 2013.Date of Publication: 01 Sep 2013. (3) E173-E183.	n=35 patients with unprotected left main (ULM) disease. Case series FD-OCT vs IVUS assessments pre- and post-PCI repeated at 1 year Follow-up 1 year	FD-OCT required more repeated pullbacks to image the ROI compared to IVUS. Mean lumen and stent areas were similar between FD-OCT and IVUS (11.24 +/- 2.66 vs. 10.85 +/- 2.47 mm², P = 0.13 and 10.44 +/- 2.33 vs. 10.49 +/- 2.32 mm², P = 0.82, respectively), whereas imaged stent length was shorter with FD-OCT. Malapposition areas and volumes were larger and more edge dissections were detected by FD-OCT. There were no clinical adverse events and no complications associated with FD-OCT at baseline and 1-year follow-up. All dissections were healed, whereas stent malapposition was still detected at follow-up.	These efficacy findings are reported in bigger studies with larger n numbers and better methodology.
Garg S, Bourantas C, and Thackray S. (2008) Suspected coronary artery dissection post-stenting, confirmed by optical coherence tomography. Heart.94 (3) (pp 335), 2008.Date of Publication: March 2008. 335-	1	OCT confirmed diagnosis which was unclear from angiography.	A case-study. Clinical outcomes from larger studies available.

Guagliumi G et al (2013). Volumetric assessment of lesion severity with optical coherence tomography: Relationship with fractional flow reserve. EuroIntervention.8 (10) (pp 1172-1181), 2013.Date of Publication: February 2013. (10) 1172-1181.	n=21 FD-OCT	Accurate volumetric measurement of the lumen profile with FD-OCT correlates more closely with FFR than standard metrics derived from single image cross-sections. vascular resistance ratio (VRR) shows promise as a method for evaluating lesion severity.	Other studies provide outcomes that are more clinically relevant.
Gonzalo N, Escaned J, Alfonso F et al. (20-3-2012) Morphometric assessment of coronary stenosis relevance with optical coherence tomography: a comparison with fractional flow reserve and intravascular ultrasound.[Erratum appears in J Am Coll Cardiol. 2012 Apr 17;59(16):1491 Note: Gonzalo, Nieve [corrected to Gonzalo, Nieves]; Fernandez-Ortiz, Antonia [corrected to Fernandez-Ortiz, Antonio]]. Journal of the American College of Cardiology 59:1080-1089.	56	Looks at OCT and IVUS for identifying haemodynamically severe coronary stenoses as determined by fractional flow reserve. OCT has moderate diagnostic efficiency, although OCT seems slightly superior to IVUS for this purpose, particularly in vessels <3mm, its low specificity precludes its use as a substitute of FFR for functional stenosis assessment.	Other studies contain outcomes that are more relevant to clinical practice.
Gonzalo N, Serruys PW, Okamura T et al. (2009) Optical coherence tomography assessment of the acute effects of stent implantation on the vessel wall: A systematic quantitative approach. Heart.95 (23) (pp 1913-1919), 2009.Date of Publication: December 2009. 1913-1919.	73	OCT allows a detailed visualisation of vessel injury post stent implantation and enables a systematic classification and quantification in vivo.	Other studies contain outcomes that are more relevant to clinical practice.
Gonzalo N, Tearney GJ, Serruys PW et al. (2010) Second-generation optical coherence tomography in clinical practice. High-	45	FD-OCT involving high-speed data acquisition demonstrated good interstudy,	Other studies contain outcomes that are more relevant to

speed data acquisition is highly reproducible in patients undergoing percutaneous coronary intervention. Revista Espanola de Cardiologia 63:893-903.		interobserver and intraobserver reproducibility for characterising plaque and evaluating stent implantation in patients undergoing a PCI.	clinical practice.
Gutierrez-Chico JL, Serruys PW, Girasis C et al. (2012) Quantitative multi-modality imaging analysis of a fully bioresorbable stent: a head-to-head comparison between QCA, IVUS and OCT. The International Journal of Cardiovascular Imaging 28:467-478.	45	There is poor agreement for minimal lumen area estimation between all the imaging modalities studied including IVUS-OCT, hence their values are not interchangeable/ OCT is the most accurate technique for measuring stent length.	Other studies contain outcomes that are more relevant to clinical practice.
Hou J, Lv H, Jia H et al. (2012) OCT assessment of allograft vasculopathy in heart transplant recipients. Jacc: Cardiovascular Imaging 5:662-663.	7	This study demonstrates that OCT, compared to IVUS, is more sensitive for early detection of CAV. IH thickness <150um is under the resolution of IVUS and can therefore only be diagnosed with OCT. Moreover, OCT provides additional information on characteristics of IH such as lipid plaques and thin fibrous caps.	Other studies contain outcomes that are more relevant to clinical practice.
Jaguszewski M et al (2013). Optical frequency domain imaging for guidance of optimal stenting in the setting of recanalization of chronic total occlusion. Journal of Invasive Cardiology 25 (7) 367-368.	n=1 case report	Case demonstrates the potential clinical role of high-resolution OFDI to optimize coronary stent implantation. OFDI may help to limit the coronary area covered by stents to the true coronary lesion.	A case-study with no additional efficacy or safety information.

Jamil Z, Tearney G, Bruining N et al. (2011) Interstudy reproducibility of the second generation, Fourier domain OCT in patients with coronary artery disease. European Heart Journal.Conference: European Society of Cardiology, ESC Congress 2011 Paris France.Conference Start: 20110827 Conference End: 20110831.Conference Publication: (var.pagings).32 (pp 854-855), 2011.Date of Publication: August 2011. 854-855.	18	FD-OCT shows excellent reproducibility and very low inter-study variability in both native and stented coronary segments. No significant differences in quantitative lumen morphometry were observed between OCT and IVUS.	Other studies contain outcomes that are more relevant to clinical practice.
Jang I-K, Bouma BE, Kang D-H et al. (2002) Visualization of coronary atherosclerotic plaques in patients using optical coherence tomography: Comparison with intravascular ultrasound. Journal of the American College of Cardiology.39 (4) (pp 604-609), 2002.Date of Publication: 20 Feb 2002. 604-609.	42	Intracoronary OCT appears to be feasible and safe. OCT identified most architectural features detected by IVUS and may provide additional detailed structural information.	Other studies contain outcomes that are more relevant to clinical practice.
Jang I-K, Tearney GJ, MacNeill B et al. (2005) In vivo characterization of coronary atherosclerotic plaque by use of optical coherence tomography. Circulation.111 (12) (pp 1551-1555), 2005.Date of Publication: 29 Mar 2005. 1551-1555.	69	OCT is a safe and effective modality for characterising coronary atherosclerotic plaques in vivo.	Other studies contain outcomes that are more relevant to clinical practice.
Jia H et al (2013). In Vivo Diagnosis of Plaque Erosion and Calcified Nodule in Patients with Acute Coronary Syndrome by Intravascular Optical Coherence Tomography. J Am.Coll.Cardiol.	n=126 patients with ACS OCT	OCT is a promising modality for identifying OCT-erosion and calcified nodule (OCT-CN) in vivo. OCT-erosion is a frequent finding in patients with ACS,	Other studies provide outcomes that are more clinically relevant.

		especially in those with non-ST-segment elevation (NSTE-ACS) and younger patients. OCT-CN is the least common etiology for ACS and is more common in older patients.	
Jiang B, Gai L, Sun Z et al. (2011) The combination of 64 multislice CT angiography and optical coherence tomography optimally characterizes coronary plaques. Acta Cardiologica 66:213-218.	28	CTCA vs. OCT and CA: CTCA best revealed the vessel wall while OCT provided optimal visualisation of the intima. The extent of coronary artery disease was best determined with CA and CTCA	Other studies contain outcomes that are more relevant to clinical practice.
Jimenez-Valero S, Moreno R, and Sanchez-Recalde A. (2009) Very late drug-eluting stent thrombosis related to incomplete stent endothelialization: in-vivo demonstration by optical coherence tomography. Journal of Invasive Cardiology 21:488-490.	1	This case illustrates the ability of OCT for in-vivo identification of stent coverage and role in evaluation of stent thrombosis.	A case-study. Clinical outcomes from larger studies available.
Khandhar SJ et al (2013). Optical coherence tomography for characterization of cardiac allograft vasculopathy after heart transplantation (OCTCAV study). Journal of Heart and Lung Transplantation.32 (6) (pp 596-602), 2013.Date of Publication: June 2013. (6) 596-602.	n=15 patients 1 to 4 years after transplant with no angiographic evidence of coronary allograft vasculopathy (CAV) FD-OCT	OCT imaging revealed 8 of 15 patients had intimal hyperplasia with an I/M ratio >1. Comparing those with I/M ratio of <=1 and >1, the median intimal thickness was greater (75 [70-101] vs 206 [97-269] mum, p = 0.03), whereas the media thickness was no different (72 [70-103] vs 94 [73-113] mum, p = 0.53). In addition, 7 of 15 patients had lipid-rich or calcified atherosclerotic	Other studies provide outcomes that are more clinically relevant.

		plaques. OCT provides high-resolution quantitative imaging of the coronary arteries and its use allows for detailed assessment of the coronary artery wall and early morphologic changes that occur after cardiac transplantation.	
Kataiwa H, Tanaka A, Kitabata H et al. (21-1-2011) Head to head comparison between the conventional balloon occlusion method and the non-occlusion method for optical coherence tomography. International Journal of Cardiology 146:186-190.	23	Compares balloon occlusion and continuous flushing OCT, finds both can be performed safely and obtained similar quality images.	Other studies contain outcomes that are more relevant to clinical practice.
Kawamori H, Shite J, Shinke T et al. (2010) The ability of optical coherence tomography to monitor percutaneous coronary intervention: detailed comparison with intravascular ultrasound. Journal of Invasive Cardiology 22:541-545.	18	Proximal coronary occlusion during OCT imaging was possibly related to underestimation of vessel sizing at distal reference. OCT might provide more detailed information on the presence of tissue prolapse, thrombus formation and edge dissection than IVUS.	Other studies contain outcomes that are more relevant to clinical practice.
Kubo T, Imanishi T, Takarada S et al. (4-9-2007) Assessment of culprit lesion morphology in acute myocardial infarction: ability of optical coherence tomography compared with intravascular ultrasound and coronary angioscopy. Journal of the American College of Cardiology 50:933-939	30	OCT is a feasible imaging modality in patient with acute myocardial infarction and allows identification of plaque rupture, fibrous cap erosion, intracoronary thrombus and TCFA in vivo more frequently than using IVUS or coronary angiography.	Other studies contain outcomes that are more relevant to clinical practice.

Kubo T, Nakamura N, Matsuo Y et al. (2011) Virtual histology intravascular ultrasound compared with optical coherence tomography for identification of thin-cap fibroatheroma. International Heart Journal 52:175-179.	96	This study compared VH-IVUS with OCT, (VH-IVUS as experimental, OCT as gold standard). Found VH-IVUS correctly identified thin-cap fibroatheroma, as determined by OCT.	Primary finding relates to VH-IVUS.
Lim C, Banning A, and Channon K. (2010) Optical coherence tomography in the diagnosis and treatment of spontaneous coronary artery dissection. Journal of Invasive Cardiology 22:559-560.	1	OCT as an aid in emergency PCI. OCT was integral not only to the diagnosis of spontaneous coronary artery dissection but also to the successful PCI of the condition.	A case-study. Clinical outcomes from larger studies available.
Lindsay A C et al (2013). Predictors of stent strut malapposition in calcified vessels using frequency-domain optical coherence tomography. Journal of Invasive Cardiology.25 (9) (pp 429-434), 2013.Date of Publication: September 2013. (9) 429-434.	n=23 PCI patients OCT before and after stent deployment	8% of all stent struts were malapposed, in the proximal part of the stent. By univariate analysis, the % of malapposed struts was found to correlate with the circumferential extent of calcification (P<=.04); Using multivariate analysis, the circumferential extent of vessel wall calcification was the only plaque feature found to correlate with the % of malapposed struts (P<=.01). Using OCT to assess vessel wall characteristics, the circumferential extent of superficial calcification seen, and not the depth, correlated well with the percentage of malapposed struts following PCI.	These efficacy findings are reported in bigger studies with larger n numbers and better methodology.
Liu W et al (2013). Is this spontaneous coronary	n=1 case report		A case-study with no

intramural hematoma or fibrotic plaque?: An inconsistent finding between optical coherent tomography and intravascular ultrasound. JACC: Cardiovascular Interventions.6 (9) (pp 983-984), 2013.Date of Publication: September 2013. (9) 983-984.			additional efficacy or safety information.
Lucarelli K, Casamassima V, Campanella M et al. (2009) Optical coherence tomography imaging in complicated acute myocardial infarction treated with primary angioplasty and AngioJet. Journal of cardiovascular medicine (Hagerstown, Md.).10 (7) (pp 581-584), 2009.Date of Publication: Jul 2009. 581-584.	1	OCT was able to identify microstructural features of atherosclerotic plaque that are associated with plaque vulnerability.	A case-study. Clinical outcomes from larger studies available.
Maeda T et al (2013). Serial three-dimensional optical coherence tomography assessment of strut coverage and intraluminal structures after drug-eluting stent implantation. Cardiovasc.Interv.Ther.	3D vs 2D OCT at implantation and follow-up	The classification and visual assessment of intraluminal structures by 3D-OCT were useful in evaluating arterial healing after EES implantation.	Other studies provide outcomes that are more clinically relevant.
Matsumoto M, Yoshikawa D, Ishii H et al. (2012) Morphologic characterization and quantification of superficial calcifications of the coronary artery--in vivo assessment using optical coherence tomography. Nagoya Journal of Medical Science 74:253-259.	39	OCT could visualise superficial coronary calcifications in detail and enable evaluation of in vivo morphologic characterisations and quantification of them.	Other studies contain outcomes that are more relevant to clinical practice.
Moharram MA, Yeoh T, and Lowe HC. (14-4-2011) Swings and roundabouts: Intravascular Optical	1	Finds OCT gave no information regarding absolute or percent plaque area, although revealed stent strut	A case-study. Clinical outcomes from larger studies available.

Coherence Tomography (OCT) in the evaluation of the left main stem coronary artery. International Journal of Cardiology 148:243-244.		position with improved precision.	
Montone RA, Cataneo L, Minelli S et al. (2012) Very late stent thrombosis complicating a previously lost and partially crushed stent: demonstration by optical coherence tomography. Cardiovascular Revascularization Medicine 13:357-359.	1	Before deciding on a discontinuation of dual antiplatelet therapy, a coronary angiography followed by an OCT run to evaluate stent coverage, healing and integration may be useful.	A case-study. Clinical outcomes from larger studies available.
Motreff P, Levesque S, Souteyrand G et al. (2010) High-resolution coronary imaging by optical coherence tomography: Feasibility, pitfalls and artefact analysis. Archives of cardiovascular diseases 103:215-226.	73	OCT provides otherwise unobtainable in vivo information, it allows further study of vulnerable plaque and for stent assessment. After a 20-examination learning curve, effectiveness is excellent.	Other studies contain outcomes that are more relevant to clinical practice.
Movahed MR, Ram V, and Arsanjani R. (2012) Optimal visualization of five different stent layers during and after percutaneous coronary intervention for recurrent in-stent restenosis using optical coherence tomography (OCT). Cardiovascular Revascularization Medicine 13:292-294.	1	OCT remains an excellent tool for assessment of lesions with instent restenosis for optimal stent assessment and treatment. To our knowledge, this case is the first case report demonstrating excellent visualization of 5 different stent layers extending back near the adventitia using OCT.	A case-study. Clinical outcomes from larger studies available.
Muramatsu T et al (2013) Intimal Flaps Detected by Optical Frequency Domain Imaging in the Proximal Segments of Native Coronary Arteries.	n=97 FD-OCT after stent implantation in patients with STEMI (8,931	OFDI identified 8 flap in 7 patients, all flaps were left untreated. In 5.1% of STEMI patients, post-procedural FD-OCT	These efficacy findings are reported in bigger studies with larger n numbers and

	frames)	identified flaps with minimal involvement of the intima in the proximal coronary arteries. There were no adverse cardiac events during 6-months follow-up. A precise interpretation of flap like structure may help decision making to avoid unnecessary procedures.	better methodology.
Nagoshi R et al (2013). Qualitative and quantitative assessment of stent restenosis by optical coherence tomography: comparison between drug-eluting and bare-metal stents. Circulation Journal 77 (3) 652-660.	n=122 OCT	The morphologic OCT patterns of the neointimal tissue (NIT) in in-stent restenosis (ISR) differed significantly between DES and BMS, probably reflecting pathologic differences. Layered and heterogeneous tissues might respond better than homogeneous tissue to simple balloon dilatation, suggesting a possible direction for OCT-based ISR treatment strategies.	Other studies provide outcomes that are more clinically relevant.
Nakamura R et al (2011). A successful treatment for in-stent restenosis using a 4-French guiding catheter with optical coherence tomography guidance. Cardiovascular Intervention and Therapeutics 26 (3) 296-300.	n=1 case report	Optical coherence tomography (OCT) image acquisition was successfully performed using a non-occlusive technique. Restenotic tissue consisting of eccentric layers was observed by the OCT.	A case-study with no additional efficacy or safety information.
Okamura T, Gonzalo N, Gutierrez-Chico JL et al. (2010) Reproducibility of coronary Fourier domain optical coherence tomography: quantitative analysis of in vivo stented	9	Demonstrates a remarkably high reproducibility for in vivo quantification of lumen area and stent area using FD-OCT. This high	Other studies contain outcomes that are more relevant to clinical

coronary arteries using three different software packages. Eurointervention 6:371-379.		reproducibility is robust when subjected to various core laboratory software solutions with different levels of automation for contour tracing.	practice.
Okamura T, Onuma Y, Garcia-Garcia HM et al. (2011) First-in-man evaluation of intravascular optical frequency domain imaging (OFDI) of Terumo: a comparison with intravascular ultrasound and quantitative coronary angiography. EuroIntervention : journal of EuroPCR in collaboration with the Working Group on Interventional Cardiology of the European Society of Cardiology 6:1037-1045.	19	FD-OCT imaging is feasible both before and after stenting and has a promising safety profile. The FD-OCT provided clear high resolution images and robust lumen measurements.	These efficacy findings are reported in bigger studies with larger n numbers and better methodology.
Parodi G, Maehara A, Giuliani G et al. (2010) Optical coherence tomography in unprotected left main coronary artery stenting. Eurointervention 6:94-99.	15	OCT assessment of vascular response after left main coronary artery DES implantation is safe and feasible. Further development of OCT imaging technology will be necessary for complete evaluation of left main coronary artery stents.	Other studies contain outcomes that are more relevant to clinical practice.
Pawlowski T et al (2013). Optical coherence tomography criteria for defining functional severity of intermediate lesions: a comparative study with FFR. Int.J Cardiovasc.Imaging	n=48 71 intermediate coronary lesions assessed using both OCT (non-occlusive method) and FFR	OCT derived minimal lumen area might be complementary to FFR measurement in identifying ischemia related lesions. Further studies are warranted to assess threshold values in relation to vessel size and location.	Other studies provide outcomes that are more clinically relevant.
Pidlaoan V, Banerjee S,	3	OCT was used to	Three case-

and Brilakis ES. (2012) Application of optical coherence tomography in the treatment of coronary bifurcation lesions. Journal of Invasive Cardiology 24:E39-E42.		optimize the procedural result. We describe 3 coronary bifurcation PCI cases, in which OCT helped guide the procedure by detecting a dissection (case 1), thrombus (case 2), and by confirming ostial vessel coverage (case 3).	studies. Clinical outcomes from larger studies available.
Prati F, Cera M, Ramazzotti V et al. (2008) From bench to bedside - A novel technique of acquiring OCT images. Circulation Journal.72 (5) (pp 839-843), 2008.Date of Publication: 2008. 839-843.	44	The non-occlusive direct modality of OCT acquisition is safe and effective.	Other studies contain outcomes that are more relevant to clinical practice.
Ramesh S, Papayannis A, Abdel-Karim AR et al. (2012) In vivo comparison of Fourier-domain optical coherence tomography and intravascular ultrasonography. Journal of Invasive Cardiology 24:111-115.	15	OCT and IVUS produce similar measurements.	Other studies contain outcomes that are more relevant to clinical practice.
Rayoo R, Tuer Z, Sharma N et al. (2011) Intracoronary optical coherence tomography for the assessment of in-stent restenosis. Heart, Lung & Circulation 20:332-335.	1	OCT was used in investigation.	A case-study. Clinical outcomes from larger studies available.
Ruiz-Garcia J et al (2013). Stent thrombosis in ostial lesion: diagnosis and treatment guided by optical coherence tomography. Revista Espanola de Cardiologia 66 (7) 586-588.	n=1 case report	Stent thrombosis in which OCT provided useful information for diagnosis, understanding the thrombotic mechanism, deciding on appropriate therapeutic strategy, and guiding PCI.	A case-study with no additional efficacy or safety information.
Sato D, Koga S, Yasunaga T et al. (2012)	2	Culprit segments were identified by	Case-studies. Clinical

Culprit segments identified by optical coherence tomography in patients with acute myocardial infarction: Two case reports.		OCT but not by either coronary angiography or intravascular ultrasound.	outcomes from larger studies available.
Saw J et al (2012). Intracoronary imaging of coronary fibromuscular dysplasia with OCT and IVUS. Catheter. Cardiovasc.Interv.		Adjunctive IVUS or OCT may aid the diagnosis of coronary fibromuscular dysplasia and we report the first of such novel images.	Other studies provide outcomes that are more clinically relevant.
Sawada T, Shite J, Garcia-Garcia HM et al. (2008) Feasibility of combined use of intravascular ultrasound radiofrequency data analysis and optical coherence tomography for detecting thin-cap fibroatheroma. European Heart Journal 29:1136-1146.	56	Evaluating the feasibility of the combined use of virtual histology-IVUS and OCT they found neither modality alone is sufficient for detecting TCFA. The combined use of OCT and VH-IVUS might be a feasible approach for evaluating TCFA (thin-cap fibroatheroma).	Other studies contain outcomes that are more relevant to clinical practice.
Secco GG, Foin N, Viceconte N et al. (2011) Optical coherence tomography for guidance of treatment of in-stent restenosis with cutting balloons. Eurointervention 7:828-834.	14	OCT measurements of strut-to-strut distance allow safe upsizing of the CB with an acceptable lumen increase before deployment of a new DES. The strategy appears of particular usefulness for a DEB strategy with no intention to implant new stents.	Other studies contain outcomes that are more relevant to clinical practice.
Smith DK, Bourenane H, Strange JW et al. (2012) Catheter-induced coronary dissection during optical coherence tomography investigation. Eurointervention 7:1124-1125.	1	The images, generated with OCT, facilitate safe and accurate delineation of arterial pathology and optimisation of stenting procedures.	A case-study. Clinical outcomes from larger studies available.
Soeda T, Uemura S,	17	Primary outcomes	Other studies

Morikawa Y et al. (5-5-2011) Diagnostic accuracy of dual-source computed tomography in the characterization of coronary atherosclerotic plaques: comparison with intravascular optical coherence tomography. International Journal of Cardiology 148:313-318.		are around noninvasive DSCT however it has been compared with OCT.	contain outcomes that are more relevant to clinical practice.
Sukiennik A, Radomski M, Rychter M et al. (2008) Usefulness of optical coherence tomography in the assessment of atherosclerotic culprit lesions in acute coronary syndromes. Comparison with intravascular ultrasound and virtual histology. Cardiology Journal 15:561-563.	1	OCT is useful as an imaging method to complement VH and IVUS in diagnostic evaluation.	A case-study. Clinical outcomes from larger studies available.
Suzuki N, Guagliumi G, Bezerra HG et al. (2011) The impact of an eccentric intravascular ImageWire during coronary optical coherence tomography imaging. Eurointervention 6:963-969.	30	Eccentric intraluminal position of the OCT image wire occurs frequently and affects calibration and interpretation of images, including length, orientation and visibility of vessel wall .structures	Outcomes more relevant to clinical practice are found in other studies.
Takarada S, Imanishi T, Liu Y et al. (1-2-2010) Advantage of next-generation frequency-domain optical coherence tomography compared with conventional time-domain system in the assessment of coronary lesion. Catheterization & Cardiovascular Interventions 75:202-206.	14	Compares FD-OCT and TD-OCT. Concludes that FD-OCT has better performance in the clinical setting and the potential to overcome several limitations of conventional TD-OCT systems.	Outcomes more relevant to clinical practice are found in other studies.
Tanimoto T, Imanishi T, Tanaka A et al. (2009) Various types of plaque disruption in culprit coronary artery visualized	1	OCT clearly revealed ruptured plaque and an intraluminal thrombus. OCT also revealed a small	A case-study with no additional efficacy or safety

by optical coherence tomography in a patient with unstable angina. Circulation Journal.73 (1) (pp 187-189), 2009.Date of Publication: 2009. 187-189.		ruptured plaque and an eroded plaque with intraluminal thrombi in a distal site remote from the culprit lesion, neither of which was visualised by IVUS.	information.
Tearney GJ, Waxman S, Shishkov M et al. (2008) Three-dimensional coronary artery microscopy by intracoronary optical frequency domain imaging. Jacc: Cardiovascular Imaging 1:752-761.	3	OCT is a viable method for imaging the microstructure of long coronary segments in patients. This technology may be useful for studying human coronary pathophysiology in vivo and as a clinical tool for guiding the management of coronary artery disease.	These efficacy findings are reported in bigger studies with larger n numbers and better methodology.
Toutouzas K, Karanasos A, Stathogiannis K et al. (2012) A honeycomb-like structure in the left anterior descending coronary artery: demonstration of recanalized thrombus by optical coherence tomography. Jacc: Cardiovascular Interventions 5:688-689.	1	OCT was used in the assessment because the angiograph was hazy.	A case-study with no additional efficacy or safety information.
Toutouzas K, Karanasos A, and Stefanadis C. (2012) Pitfalls of angiography in the assessment of atherosclerosis: the role of optical coherence tomography. Journal of Invasive Cardiology 24:246-247.	1	OCT can minimise diagnostic errors.	A case-study with no additional efficacy or safety information.
Tu S, Xu L, Ligthart J et al. (2012) In vivo comparison of arterial lumen dimensions assessed by co-registered three-dimensional (3D)	74	Comparison of coregistered 3D quantitative coronary angiography and invasive imaging data suggests a bias	Outcomes more relevant to clinical practice are found in other studies.

quantitative coronary angiography, intravascular ultrasound and optical coherence tomography. The International Journal of Cardiovascular Imaging 28:1315-1327.		towards larger lumen dimensions by IVUS and by OCT, which was more pronounced in larger and tortuous vessels.	
Viceconte, N et al (2013). Frequency domain optical coherence tomography for guidance of coronary stenting. International Journal of Cardiology 166 (3) 722-728.	398 OCT pull-backs in 108 patients Case series	The 371 pull-backs, had an average length of 35 mm and encompassed 193 lesions. In the pre-intervention group deferral of treatment was decided for 13/68 pullbacks (19.1%), whereas strategies different from conventional predilatation (e.g. thrombectomy, rotablator, cutting-balloon) were decided in 23 cases (33.8%). After full lesion dilatation 96 pullbacks (25.9%, pre-stenting group) were performed, 46 (47.9%) of which suggested proceeding directly with stenting while 50 (52.1%) suggesting further treatment. Out of the 207 pullbacks in post-stenting group, 29 (14%) suggested new stent implantation because of dissection or residual stenosis; 64 (30.9%) suggested further optimization with high pressure/larger-sized balloon. No major complications were observed. Five cases (4.6%) of contrast-induced nephropathy	These efficacy findings are reported in bigger studies with larger n numbers and better methodology.

		were reported. Repeated examinations with FD-OCT can be safely used to guide stent selection and improve stent expansion and apposition.	
Won, H et al (2013). Optical coherence tomography derived cut-off value of uncovered stent struts to predict adverse clinical outcomes after drug-eluting stent implantation. The International Journal of Cardiovascular Imaging 29 (6) 1255-1263.	489 patients treated with DES OCT follow-up: median 489 days	The best cut-off value of % of uncovered struts for predicting MSE was 5.9%. A greater percentage of uncovered struts (the cut-off value of >=5.9 % uncovered struts) might be significantly associated with occurrence of MSE after DES implantation.	Study detected cut off value of uncovered sturts by OCT for predicting adverse clinical outcomes. Other studies provide outcomes that are more clinically relevant.
Wong DT et al (2013). In-stent thrombosis due to neoatherosclerosis: insight from optical coherence tomography. Journal of Invasive Cardiology 25 (6) 304.	Case report	Study highlights the use of OCT in identifying the precise mechanism of the stent thrombosis, which helped guide the appropriate intervention.	A case-study with no additional efficacy or safety information.
Wykrzykowska JJ, Ligthart J, Lopez NG et al. (2012) How should I treat an iatrogenic aortic dissection as a complication of complex PCI? EuroIntervention.7 (9) (pp 1111+1117), 2012.Date of Publication: January 2012. 1111+1117-	1	OCT was useful in this investigation.	A case-study. Clinical outcomes from larger studies available.
Yamamoto M, Takano M, Murakami D et al. (7-1-2011) Optical coherence tomography analysis for restenosis of drug-eluting stents. International Journal of Cardiology 146:100-103.	25	OCT imaging may be useful for selection of appropriate therapeutic strategies.	Outcomes more relevant to clinical practice are found in other studies.
Yonetsu T, Kakuta T, Lee	125	OCT may be useful in	Aims do not

T et al. (2011) Impact of plaque morphology on creatine kinase-MB elevation in patients with elective stent implantation. International Journal of Cardiology.146 (1) (pp 80-85), 2011.Date of Publication: 07 Jan 2011. 80-85.		stratifying the risk for nonemergency stent implantation.	include assessing OCT and primary results do not consider OCT.
Yoon HJ, Hur SH, Kim SK et al. (2011) A case of in-stent neointimal plaque rupture 10 years after bare metal stent implantation: intravascular ultrasound and optical coherence tomographic findings. Sunhwangi 41:671-673.	1	OCT was useful in this investigation.	A case-study. Clinical outcomes from larger studies available.
Yoshikawa D, Ishii H, Aoyama Y et al. (2010) Optical coherence tomography images of a coronary artery aneurysm in an infarct-related artery 6 months after bare-metal stent implantation. Jacc: Cardiovascular Interventions 3:1300-1302.	1	OCT was useful in this investigation.	A case-study. Clinical outcomes from larger studies available.
Yoshikawa D, Ishii H, Aoyama Y et al. (2010) Characteristics of in vivo images from an in-stent restenosis lesion of a saphenous vein graft after bare-metal stent implantation: Assessment using optical coherence tomography. Journal of Cardiology Cases.1 (3) (pp e151-e153), 2010.Date of Publication: June 2010. e151-e153.	1	OCT was useful in this investigation.	A case-study. Clinical outcomes from larger studies available.
InVivo Diagnosis of Plaque Erosion and Calcified Nodule in Patients With Acute Coronary Syndrome by	n=126 with ACS OCT	Optical coherence tomography is a promising modality for identifying OCT-erosion and OCT-CN.	Other studies provide outcomes that are more clinically

Intravascular Optical Coherence Tomography. Journal of the American College of Cardiology 2013.			relevant.
OCT Compared With IVUS in a Coronary Lesion Assessment The OPUS-CLASS Study. Jacc: Cardiovascular Imaging 2013.	n=100 prospective study using angiography, FD-OCT, and IVUS	In the clinical study, the mean MLD measured by QCA was significantly smaller than that measured by FD-OCT and the MLD measured by IVUS was significantly greater than that measured by FD-OCT although a significant correlation was observed between the 2 imaging techniques. The results of this prospective multicenter study demonstrate that FD-OCT provides accurate and reproducible quantitative measurements of coronary dimensions in the clinical setting.	Other studies provide outcomes that are more clinically relevant.

Appendix B: Related NICE guidance for optical coherence tomography to guide percutaneous coronary intervention

Guidance	Recommendations
Technology appraisals	**Guidance on the use of coronary artery stents. NICE technology appraisal 71 (2003)** 1.1 Stents should be used routinely where percutaneous coronary intervention (PCI) is the clinically appropriate procedure for patients with either stable or unstable angina or with acute myocardial infarction (MI). 1.2 It is recommended that when considering the use of a bare-metal stent (BMS) or a drug-eluting stent (DES) the decision should be based on the anatomy of the target vessel for stenting and the symptoms and mode of presentation of the disease. 1.3 The use of either a Cypher (sirolimus-eluting) or Taxus (paclitaxel-eluting) stent is recommended in PCI for patients with symptomatic coronary artery disease (CAD), in whom the target artery is less than 3 mm in calibre (internal diameter) or the lesion is longer than 15 mm. This guidance for the use of DES does not apply to people who have had an MI in the preceding 24 hours, or for whom there is angiographic evidence of thrombus in the target artery. 1.4 If more than one artery is considered clinically appropriate for stenting then the considerations in Section 1.3 apply to each artery. 1.5 This guidance specifically relates to the present clinical indications for PCI and excludes conditions (such as many cases of stable angina) that are adequately managed with standard drug therapy.

Appendix C: Literature search for Optical Coherence Tomography to guide percutaneous coronary intervention

Databases	**Date searched**	**Version/files**	**No. retrieved**
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	30/10/2013	Issue 10 of 12, October 2013	1
Database of Abstracts of Reviews of Effects – DARE (CRD website)	30/10/2013	Issue 10 of 12, October 2013	0
HTA database (CRD website)	30/10/2013	Issue 10 of 12, October 2013	0
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	30/10/2013	Issue 10 of 12, October 2013	1
MEDLINE (Ovid)	30/10/2013	1946 to October Week 3 2013	105
MEDLINE In-Process (Ovid)	30/10/2013	October 29, 2013	68
PubMed	30/10/2013	N/A	42
EMBASE (Ovid)	30/10/2013	1974 to 2013 Week 43	207
CINAHL (NLH Search 2.0 or EBSCOhost) (delete if not requested)	30/10/2013	N/A	28
JournalTOCS	30/10/2013	N/A	19

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	Tomography, Optical Coherence/
2	(Optic* adj3 Coherenc* adj3 Tomograph*).tw.
3	OCT.tw.
4	(Optic* adj3 frequenc* adj3 domain* adj3 Imag*).tw.
5	OFDI.tw.
6	(dragonfly adj3 catheter*).tw.
7	(ilumien adj3 system*).tw.
8	(lunawave adj3 system*).tw.
9	(fastview adj3 catheter*).tw.

10	or/1-9
11	coronary vessels/
12	Coronary Artery Disease/
13	coronary occlusion/ or exp coronary stenosis/ or coronary restenosis/
14	Coronary Thrombosis/
15	((coronar* or arter*) adj3 (infarct* or obstruct* or vessel* or occlus* or stenosis* or restenosis* or Thrombosis* or stent* or patenc* or atherosclerosis)).tw.
16	(Stent* adj3 (visualization or deployment or thrombosis)).tw.
17	imag*.tw.
18	((intravascular or intracoronary) adj3 imag*).tw.
19	15 and 17
20	11 or 12 or 13 or 14 or 16 or 18 or 19
21	10 and 20
22	Animals/ not Humans/
23	21 not 22
24	limit 23 to english language